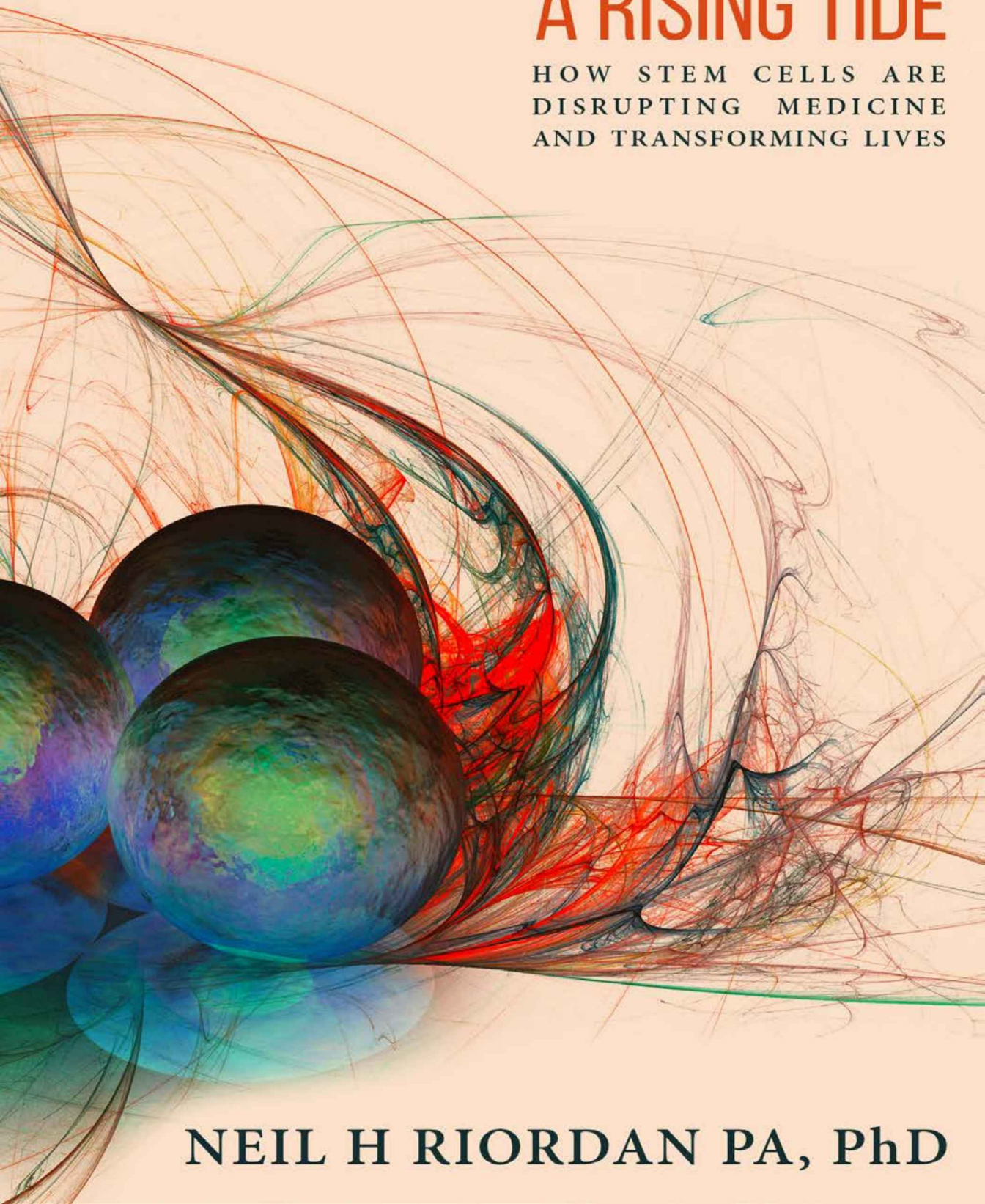
STEM CELL THERAPY

A RISING TIDE

HOW STEM CELLS ARE DISRUPTING MEDICINE AND TRANSFORMING LIVES



NEIL H RIORDAN PA, PhD

"Neil takes readers on a riveting journey through the past, present and future of stem cell therapy. His well-researched, educational and entertaining book could change your life. I highly recommend it."

Tony Robbins, NY Times #1 Bestselling Author

"100 years old will soon become the new 60. Stem cells are a key therapeutic to enable this future. Dr. Riordan's book is your guide to why this is true and how you will benefit. A must read for anyone who cares about extending their healthy lifespan."

Peter H. Diamandis, MD; Founder, XPRIZE & Singularity University; Co-Founder, Human Longevity, Inc.; Author of NY Times Best Sellers *Abundance* and *Bold*

Stem cells are the repair cells of your body. When there aren't enough of them, or they aren't working properly, chronic diseases can manifest and persist.

From industry leaders, sport stars, and Hollywood icons to thousands of everyday, ordinary people, stem cell therapy has helped when standard medicine failed. Many of them had lost hope. These are their stories.

Neil H Riordan, author of *MSC: Clinical Evidence Leading Medicine's Next Frontier*, the definitive textbook on clinical stem cell therapy, brings you an easy-to-read book about how and why stem cells work, and why they're the wave of the future.

"I'm the luckiest guy in the world. Stem cells have given me my life back."

Sam Harrell – Football coach and Multiple Sclerosis patient

"I never want to go back to autism before stem cells."

Marty Kelly – Parent of a child with autism

NEIL H RIORDAN, PA, PhD

Neil H Riordan is an accomplished scientist and developer of regenerative medicine therapeutics, with more than 70 peer reviewed publications and more than 40 patents and patent applications to his credit. He is the author of MSC: Clinical Evidence Leading Medicine's Next Frontier, a groundbreaking compilation of stem cell studies for more than 30 medical conditions, with over 800 references to peer-reviewed articles. Dr. Riordan founded Medistem Panama, a leading stem cell laboratory and research facility that is ISO 9001 certified and fully licensed by the Panamanian Ministry of Health. He also founded the Stem Cell Institute in Panama, where his mesenchymal stem cell technologies continue to be implemented in patients, now numbering in the thousands, with autoimmune and degenerative diseases and injuries.

Stem Cell Therapy
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Neil H. Riordan

Stem Cell Therapy: A Rising Tide
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Layout design by www.iPublicidades.com

Illustrations by
Blake Swanson – Innercyte: Medical Art Studios
Steve Lewis – Blausen Medical
Stem Cell Institute & Riordan-McKenna Institute

Covert design by n23art

Printed in the United States of America.
First Printing: 2017
ISBN: 978-0-9990453-0-5

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Foreword

As I read this book, I became very emotional. I had to go back about 28 years ago when my wife and I sat in a doctor's office and listened to a neurologist list in grim detail how our beautiful three-year-old son Ryan would spend his next 20 years. The doctor told us there was nothing that they could do at that time. He suggested that we do everything we could to keep Ryan active in order to maintain the strength he had as long as possible. And hopefully in the next 20 years they might find a cure for muscular dystrophy. The prognosis changed our lives forever. It was a very painful time for all of us.

As I continued to read about all of the patients who have been treated by Dr. Riordan, I realized that we all had one thing in common: traditional medicine had given up on us. There was nothing that could be done. Our own government, founded on the premise of life, liberty, and the pursuit of happiness, had evolved into overreaching bureaucracy that would attempt to prevent us from seeking lifesaving alternative treatments.

But once again, we all had something else in common. We found a man who was willing to do everything in his power to offer us options and give us hope for the future of our loved ones. Dr. Riordan has truly dedicated himself to his profession as a medical pioneer. He has sacrificed everything he has to give those who have been told there are no options a fighting chance and real hope for the future.

Dr. Riordan has never wavered in the face of scrutiny. It takes true courage to stand up to the often judgmental "traditional" medical community—those who act offended when you suggest that there might be a different way.

Fortunately for all of us, Dr. Riordan had the foresight to look beyond the walls of traditional medicine and fight the fight for us. I encourage you to read this book, and not just the chapters related to your condition. As a whole, the book lays out Dr. Riordan's courageous and successful journey through his stories and the stories of his patients.

Thank you, Dr. Riordan, for all that you have done for us and our families. You truly are a hero!

George Benton, Ryan's father

Introduction

BY ARNOLD CAPLAN, PHD

Neil Riordan, PhD, PA is a pioneer of the highest order, in some ways like John Glenn or Neil Armstrong. Neil has ventured where the routes were uncharted and the dangers huge. His rocket of cell therapy was launched on a rickety platform filled with hopes and dreams, and powered by an engine of money. This pioneer has hacked his way through the jungle of naysayers and has produced miracles of enormous proportions. He has taken our scientific dreams and translated them into a high-caliber medical facility that does good by offering exposure to cell therapy treatments that we working scientists only dream about.

Although there are those in my professional realm who would say that Neil is a medical "cowboy" who "experiments" with human subjects, I would say that he is providing access to therapies that are no more experimental than one sees every single day in the surgical suites of major medical centers. In such situations, the surgeon is "forced" to improvise because of the complexity of the wound field. Such improvisation sometimes involves using materials that are not approved but that the surgeon "feels" will work well in the situation he faces. For example, human decellularized skin from dead people was approved for topical applications for ulcerated wounds in diabetic patients. But these "membranes" are fabulous for closing abdominal surgical wounds in hernia repair operations and have changed the way such closures are done. This surgical improvision, originally performed by a "cowboy" surgeon, is now the standard of care. We move forward in medicine by the skill and insightful work of pioneers—some with IRB approval and some not. Riordan's procedures with MSCs currently have IRB approvals.

In a sense of transparency, let me say that I have accepted honoraria from Neil Riordan and gifts of hotel rooms, meals, and, indeed, infusions of MSCs. These all have monetary value, but none influences my opinion. The monetary success of Neil's enterprises evoke jealousy in some entrepreneurs, but Neil's continual reinvestment of money into his next medically successful enterprise displays his true motives—the advancement of a medically necessary science despite great obstacles. The key to his success is in the enormously high quality of his facilities; the people, doctors, nurses, receptionist, PR team, etc. are *all* highly principled and care about the patients they serve. These people care about what they do because Neil recruits them for their skills and attitude. He does not discuss this in this book, but they are present on every page. He talks about Dr. Paz, but he does not tell you of his long medical experience and his reputation in the United States and in Panama for caring and experienced medical judgements. In all of Neil's clinics, quality control labs, hotels for patients, and restaurants where they eat, the staff behind the scenes are dedicated to providing the highest quality medical care possible. Some clinics and hospitals in the United States could take lessons from the Riordan gang. That said, the cell-based therapies Neil's clinics provide have not all been approved and tested by double-blind, placebo control and rigorously monitored clinical trials, although such trials are currently underway. But, like innovative surgeons, these open-label uses have proven effective, as hopefully we will see in published peer-reviewed reports of his studies.

Each chapter of this book recounts the personal stories of how Neil's unwavering confidence that cell-based therapies with MSC preparations from fat, marrow, or umbilical cords can make a medical difference. Neil made medical tourism work, and what he has done is highly laudable, not only because of the patients he has helped, but because of the laws that have been written to support cell-based therapies in Panama. This book is not what I pleaded with Neil to write, however. I have, for many years, begged him to give us outcome reports of his many patients: what they have as clinical problems, what they walk in with, and the longitudinal outcomes after the cell infusions. Hopefully these will be forthcoming, but they are not in this book. What is here in these pages is, none-the-less, amazing.

I first learned about Neil's clinic in Costa Rica and thought his procedures and therapies were brilliant. And these were crude compared to those currently underway in Panama. The Panama GMP-production facilities, his offices and treatment rooms, and the products including MSCs from umbilical tissue are of the highest quality. These are the vehicles and the platform that allow him to write this treatise of the therapies they provide. It is a shame that we have to fly to Panama to have access to these therapies instead of having them available in the United States. How long will it take for such therapies to be available to the patients covered by Medicaid or Medicare instead of those from Beverly Hills or Long Island who can afford to travel to Panama?

Almost daily I receive emails from people who want access to "stem cell" treatments. I tell them that I am just a PhD researcher and cannot suggest an avenue of treatment for medical issues. If you have this book in hand, read the chapters. They are honest, open, and spellbinding. While Neil is not a medical doctor, his clinical experience as a physician assistant along with his research background have prepared him for the serious medical issues for which Neil has organized cell therapy treatments, often with quite significant outcomes. Neil is certainly a student of the medical arts and an expert using innovative treatments. I have talked to patients of Neil's clinics and their family members about their treatments; the stories told in this book are just the tip of the iceberg. This is an interesting book and an interesting and gutsy journey of Neil Riordan. His physician father would be proud to recognize Neil's passion and medical achievements.

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January 15, 2017

Chapter Thirteen

AUTISM—PROGRESS, NOT REGRESSION

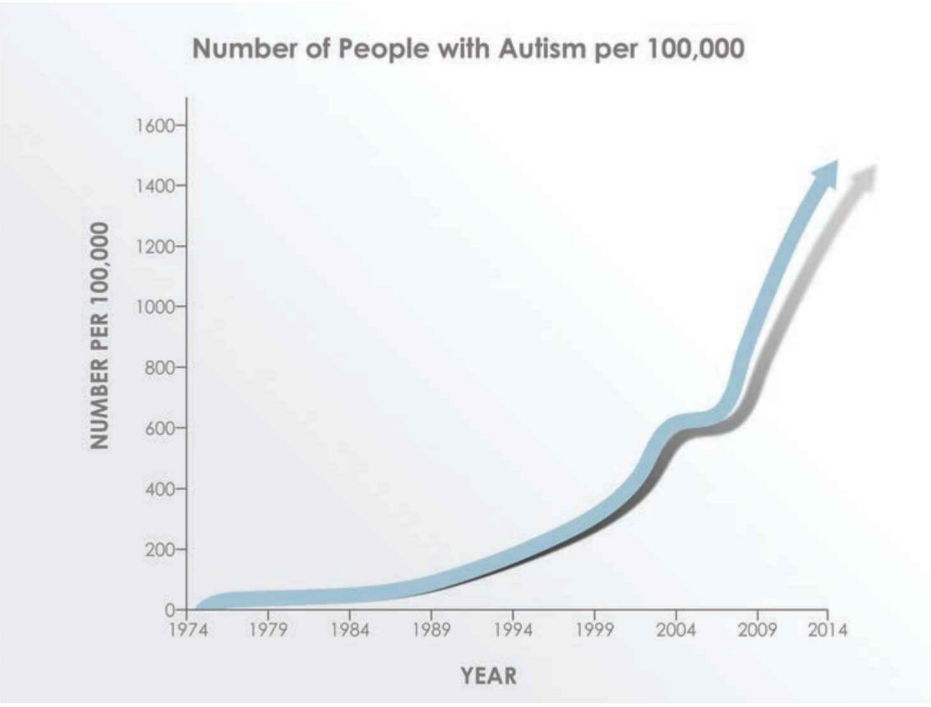
At our clinic in Panama we treat many people who have chronic conditions that their doctors have told them they have little hope of curing, but none of these diseases engages my heart the way autism does. Many people who come down with chronic diseases are shattered by how it changes their lives and rearranges plans for the future. Unlike diseases that come late in life, with autism the shattering is often more brutal and almost always affects the entire family.

Many parents of autistic children realize their child is different early on—typically between one and two years of age—and end up receiving a diagnosis from their family physician. However, there is a subset of families with an autistic child that have an entirely different story: the child is happy and healthy, making all his developmental milestones, and then suddenly one day it all stops. He is limp, unresponsive to the smiles and hugs of his parents and, in many cases, fills his days with repetitive behaviors that are disturbing to watch, such as rocking back and forth, repeating the same phrases, or doing the same activity with blocks or cars over and over again.

For families living with autism, the pain is so much stronger because of the loss of hope. When you are stricken with a chronic condition at the age of 50, you've already lived a large part of your life and made some good memories. When a small child is diagnosed with a condition as persistent as

autism, the future looks bleak. Parents can't help but worry about how their child will survive as an adult and what special care he will need after they have gone.

Unfortunately, autism is widespread, and the number of children diagnosed with it is increasing. Today one in every 68 children is diagnosed with autism, making it more prevalent than childhood cancer, juvenile diabetes, and childhood AIDS combined. And government statistics suggest that the number of children diagnosed with autism is increasing at a rate of between 10 and 17 percent annually. This might be because we are getting better at diagnosing it, or it may be due to an increase of whatever is causing it—be it environmental influences or the result of multiple genetic factors. Other research points to the mother having been exposed to viral infections or chemical insults. Some evidence collected over the last 30 years suggests that autism may be caused by inflammation of the central nervous system. This is where, we have found, stem cell therapy can help because of stem cells' ability to help mediate inflammation.



From data found in Centers for Disease Control and Prevention (CDC) website at https://www.cdc.gov/ncbddd/autism/data.html

Mesenchymal Stem Cells for Treatment of Autism

Autism spectrum disorder (ASD) refers to a group of brain development disorders that affect communication skills and social interaction to varying degrees of intensity, with significant impact on the patient, his or her family, and society. The mechanisms that cause ASD have not been completely determined,[7] and there is currently no cure. Treatment is focused on behavior management; medical intervention usually targets symptoms, for example with antipsychotic medication in certain cases.[8] There is a pressing need for different therapeutic approaches,[9] especially those focused on what is known so far about the biological processes associated with ASD.

Recent studies have found that there may be a link between ASD, the immune system, and inflammation. Children with ASD have higher measures of certain chemokines (signaling proteins secreted by cells, in this case MDC and TARC) that are expressed locally by inflamed tissues, with higher levels in those with more severe ASD symptoms.[10] Likewise, children with ASD have been found to have significantly higher inflammatory Th1 cytokine (IL-12 and IFN-γ) levels in their blood compared to similar-aged children.[11] Proteins that are involved in binding white blood cells to blood vessel walls (an important step of inflammation) have been found in significantly high levels in children with ASD.[12] After a 26-week treatment with the dietary supplement luteolin, a subset of children with ASD showed a reduction in levels of inflammatory cytokines TNF-α and IL-6, which was strongly associated with an improvement in behavior.[13] As in this trial, we are finding that response to treatment varies by subset of ASD children. Detecting biomarkers to identify such subsets is key in treating children with this disorder.

Children with autism have immune dysregulation and increased inflammation. Because the immune and nervous systems are closely interconnected, several immunological abnormalities have been detected in the nervous system of autistic children. Inflammatory compounds have been found in the brains and bloodstream of autistic children.[1,2,3] And children with autism have an autoimmune-like condition that several lines of reason suggest might play a causative role.[4] First, several types of autoantibodies have been found in autistic children. Second, family members of autistic children are more likely to have autoimmune conditions. And third, autism has been

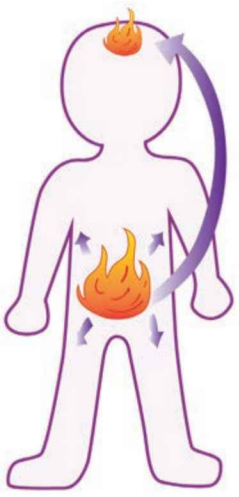
About 20 percent of children with ASD have gastrointestinal symptoms, with greater symptom severity in those with ASD measures of irritability, anxiety, and social withdrawal.[14] High sensitivity (hypersensitivity) to stimulus (auditory, visual, touch) is a common trait of ASD; a study of 2,973 children with ASD found a highly significant rate of over-responsivity to sensory stimulus in those who had gastrointestinal symptoms.[15] Inflammation in both the upper and lower intestinal tract has also been reported,[16] and a test for certain genes along with markers for inflammation were able to correctly identify ASD in 83 percent of cases.[17] This level of constant inflammation originating in the gut might cause alterations in the structure of the brain; it has been shown that cerebral white matter is disproportionately larger in children with ASD[18] and that neuroinflammation and enlarged white matter of the brain likely co-occur.[19] Recent reviews have highlighted growing evidence of neuroinflammation in children with ASD[20] and that the mechanisms of said inflammation may contribute to ASD,[21] stressing the need for treatments targeting this aspect of the condition. Our group has been proposing since 2007[22] that the characteristics of mesenchymal stem cell (MSCs) make them a viable treatment option to address the inflammatory and immunological issues associated with ASD—a double-blind, placebo-controlled trial of MSC treatment in children with ASD would be ideal to demonstrate this.

The anti-inflammatory effects of mesenchymal stem cells and their secretions[23] have been demonstrated for several inflammatory conditions,[24,25,26,27] making MSC therapy a very promising treatment for ASD patients.[28] Clinical trials have already demonstrated that treatment with MSCs is safe for ASD.[29] Children treated with a combination of umbilical cord MSCs and other umbilical cord cells showed significant differences in visual, emotional, and intellectual responses and nonverbal communication among other measures.[30] In another study, children with ASD were treated with cells derived from bone marrow, including MSCs; global improvements were observed for 96 percent of patients, including behavior patterns (66 percent), social relationships (90.6 percent), and speech, language, and communication (78 percent).[31]

Several clinical trials are currently approved and ongoing on ClinicalTrials.gov to treat ASD with bone marrow MSCs, adipose-derived MSCs, and umbilical cord MSCs.[32,33,34,35,36]

associated with an autoimmune-like bowel condition similar to Crohn's disease. And not only do children with autism have more inflammation and immune imbalance, but they also produce fewer anti-inflammatory compounds,[5,6] which only adds to their already excessive inflammation.

Our team wrote a scientific journal article (referenced above) about the rationale for using umbilical cord stem cells for autism in 2007. It was published in the *Journal of Translational Medicine* and it is one of the most accessed and cited articles—accessed more than 74,000 times.



Inflammation in the gut affects inflammation in the brain.

If inflammation and immune dysregulation are a cause of the symptoms of autism, then treating this inflammation might help to ease symptoms. We speculated that if we could inject mesenchymal stem cells into children who suffered with autism, those cells would secrete factors that quell inflammation and help to balance the immune system. If the cells worked, as they had done with so many other conditions, it was possible that we could really help these children and their families battle against this punishing condition and live more normal lives, as we did with Anthony.

Anthony Guerriero was developing normally. He talked and walked before his first birthday and met all of his developmental and behavioral milestones—that is, until about 18 months. He suddenly stopped trying to interact and became difficult to engage. He wouldn't look when his name was called and slowly lost all the vocabulary he had gained. He was officially diagnosed with autism at age two. "He didn't know who he was or who

we were. He was mute for two years. It was difficult," said John Guerriero, Anthony's dad.

Anthony became hyperactive, climbing on furniture, bouncing, jumping—even walking on countertops. It was like he was trying to escape something he didn't have the words to describe. "He wasn't comfortable in his own skin," John said.

The reason doctors use the word *spectrum* is to acknowledge that there is a wide range of behaviors that fall under the umbrella diagnosis of autism. With most diseases, you either have it or you don't. With autism, a child can be highly functioning and able to talk freely and socialize but still have some significant delays in processing the stimuli that bombard him every day. Or a child can be severely affected by the condition—withdrawn, uncommunicative, and lost in his own world. One common aspect of the condition, no matter where the child is on the spectrum, is that the earlier the parents establish therapy to help the child, the more effective that therapy is in the long run. They call this the *autism window*, the time between the ages of two and seven when the various therapies available for speech, motor skills, and socialization can have the biggest impact on correcting the condition.

Anthony underwent a wide range of therapies—behavioral, occupational, physical, speech, biomedical, and dietary—as most autistic children do. While he made progress and gained some speech, he still struggled with processing and expressive language, and he continued to have sensory challenges, digestive issues, and allergies.

Anthony's parents first heard about stem cell treatment from a prominent autism doctor, but when they looked into it, the cost seemed prohibitive. But when it was mentioned again by the parents of another autistic child, and again by a family member, they decided to do some research. They reached out to a mother on Facebook who had taken her child—who had symptoms and behaviors similar to Anthony—down for treatment. They were so impressed by her child's improvements that they decided to try to raise money for the treatment. When the mayor of their town heard about their intentions, he offered to hold a fundraiser for them, which allowed them to come down for treatment in 2015.

After his first treatment, his parents noticed right away that his skin became much softer, "like he had found the fountain of youth," said his dad. The positive changes continued when they arrived back home. Anthony began asking for new foods that he normally didn't eat. Before his treatment, he would only eat a few foods because most foods brought him digestive pain. "He put on so much weight and filled out. He's so healthy," noted his father.

His behavior also changed. He stopped climbing on furniture inappropriately. "He does normal boy stuff now. And he's super calm," John said. He was able to sit in one place for his sister's two-and-a-half-hour dance recital—an impossibility just the year before. "Last year he would have lasted one minute, and it would've been a rough day for all of us!"

Anthony's best improvement was his new connection to his brother and sister. "Now he's talking to us and his siblings. Before treatment he didn't have a relationship with his brother. He was off in his own world. Now they are best friends. The three of them are inseparable."

I've seen how powerful these cells can be in causing a dramatic turnaround in children who seemed so closed off and isolated from the world. Time after time, if the parents are willing to come back for a second treatment with stem cells, they report back that their child has made huge leaps forward toward being just a normal kid with the same issues and challenges as his or her peers.

Anthony came back for a second treatment. We saw with Anthony the same behavior we've seen with so many autistic kids who return for subsequent treatment—they actually look forward to it. First-time treatments for autistic children can be difficult. With their heightened sensitivities, need for routine, and young age, blood draws and injections can be intimidating. That's why we have partnered with autism experts from around the world to help us design an autism treatment room specially dedicated to comforting these kids. From the colors of the walls to the added touches of ambiance, the autism treatment room is designed from the ground up to help make the treatment easier for autistic children. But for subsequent treatments we often find the children eager and ready, holding out their arms to us for injections because they know it means they will feel better soon. When

Anthony returned for his second treatment, on the day of his first injection he woke up asking for stem cells.

Shortly after returning home from his second treatment, Anthony asked that his harness be removed when he rode the bus. Before treatment he had to be harnessed to his seat because he would spontaneously try to escape the bus when it stopped or even jump into the bus driver's lap while he was driving. But Anthony felt ready "to be a big boy." He no longer had trouble sitting still on the bus without his harness.

Within about a month of his second treatment Anthony's speech and conversation really took off. He engaged in imaginative play for the first time ever. And he became able to communicate when he wasn't feeling well, which makes the job of his parents so much easier. Autistic children are often suffering from ailments they do not have the ability to describe. When Anthony's molars were loose, he was able to say, "My teeth hurt here," something most parents take for granted.

Eight weeks after his second treatment his parents were calling him "blabber mouth" while remembering a time when they wondered if he would ever make a single sound again. He began telling jokes and poking fun at his dad. "This is going to be the best year of our lives," John said.

Six months after his second treatment he asked to go back to speech therapy, something he had previously asked to be taken out of because it was so stressful for him. "I can't make this stuff up—looks like it may be time for speech therapy again," John said.

Kenneth Kelley's story began a bit differently than Anthony's. When he was six months old his mother took him with her to a dental appointment where she was having her amalgam fillings removed. He slept on the floor in his carrier during the procedure, unknowingly inhaling the vaporized mercury fumes. The next day, they came back for another round. By his next doctor appointment, he had fallen off the growth chart and was having trouble nursing. He seemed weaker and his babbling never progressed. His first birthday came and went and he was no closer to walking or talking than

he had been months before. His pediatrician didn't see a problem. Nor did the next few doctors his parents consulted. They finally found a doctor who listened to their concerns, and at the age of two Kenneth was diagnosed with autism. His parents set him up with the conventional behavioral and speech therapy, but by the age of four he still had no vocabulary. The doctors said, "Maybe he's a late speaker."

At age five, Kenneth received 38 vaccinations over an eight-week period so that he could catch up with the vaccine schedule required for him to attend school. That's when his behavior took a turn for the worse. "His autism escalated probably 100-fold," said Marty Kelley, his mother. He became aggressive. When meeting new people, he would show off, shout and scream, demand attention, jump on furniture, throw things, crawl on the floor, take off his clothes. He would yell, "shut up," to his family or to strangers. He would try to run away sometimes and would carry his baby sister with him out into the road. Some days he would scream from morning until night. He could not dress himself and would put up a fight when his parents dressed him. He was still in diapers. There was very little he had mastered by that age. He needed to be shown how to do everything.

His parents went to work researching options for their son. They learned about biomedical treatments and dietary methods. It wasn't until Ken tested for mercury that his parents realized what had happened. Those two days in the dental office inhaling mercury had taken their toll. The doctors had never seen a mercury level so high. Kenneth underwent therapy to help remove the mercury, and at the age of five and a half, he began hyperbaric oxygen therapy, which helps to bring more oxygen to areas of the brain that are hypoperfused, or not getting enough oxygen, a common feature in children with autism. The therapy did help him develop some speech and become calmer, but Kenneth still had a long way to go.

Kenneth's parents continued with a range of biomedical treatments, visiting some of the top autism doctors in the world. They spent $300,000 on treatments and implementation of different protocols. Some treatments and therapies helped to a degree, and others made him worse. After two years of hyperbaric oxygen therapy—the therapy his parents felt had worked best—his improvements did not increase.

At age eight he still couldn't answer "who, what, where, when, why" questions. "What was left to do? We had done it all," Marty said. He was on the severe end of the autism spectrum and had also been diagnosed with severe mental retardation. "There is nothing you're going to be able to do with this child," the doctors told them.

Kenneth's parents became aware of stem cell therapy at that time when they saw a news story about another autistic boy who had been treated at our clinic—our first autistic patient, in fact. They talked to the boy's father and followed his progress. "I didn't believe the results they were getting at first," Marty said. But they were so impressed with his progress and knew they needed a new approach, so they decided to apply for stem cell treatment at our clinic.

Fewer than one hundred patients had used stem cells for autism at that time. "We knew that we would be out a lot of money if it didn't work. We also knew we would always wonder 'What if?' if we didn't try." Kenneth came to our clinic in Costa Rica in 2009 at age eight.

At the time, he had the vocabulary of a four-year-old, the body of a five-year-old, and he was still in diapers. "Do you know what it is like for your child to not be able to speak to you? To not be able to tell you how his day was? What he wants to be when he grows up? What his favorite color is?" Kenneth's mom summed up what it's like to live as a parent of an autistic child.

Within days of his stem cell treatment he began talking more and using more common sense, but his parents were hesitant to attribute the changes to stem cells. A week later he brought up an event from the past—something he had never done before. It stopped his mother in her tracks. Within two weeks of treatment his speech improved by 20 percent.

Within six months of his first treatment Ken began to read, his abstract thinking had improved, he exhibited more self-control, spoke more clearly, was more aware, could do math problems and write simple sentences—and finally, he no longer needed to wear diapers. His screaming and inappropriate behavior stopped. "He has emerged daily before our eyes," said his mom.

A year later, the Kelleys returned for a second treatment, this time to our clinic in Panama, hoping to see even more gains. And they did. He continued to improve his reading, speech, and behavior. By the next year, at age ten, his conversational skills were on par for his age. And he returned for a third treatment.

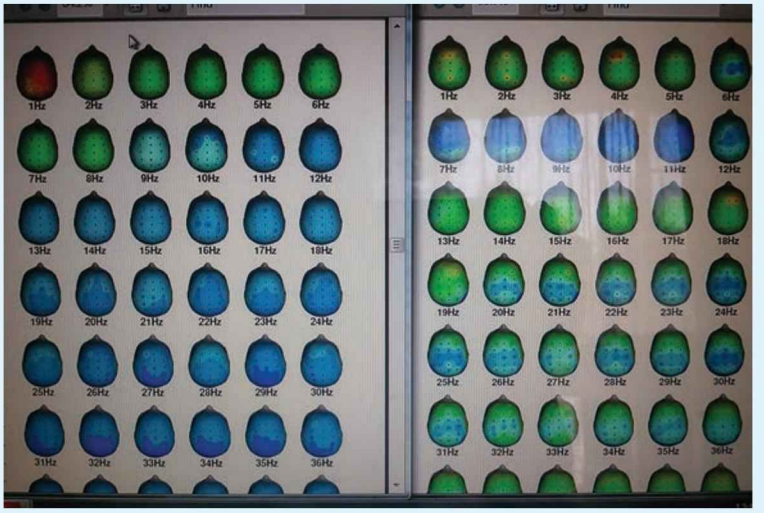
"Kenneth is a miracle," said Marty. "I never want to go back to autism before stem cells." After his third treatment she said, "The results from stem cells can be seen every day in his amazing thoughts and vast imagination. Watching my son play today, it's hard to believe where he was just a few short years ago."

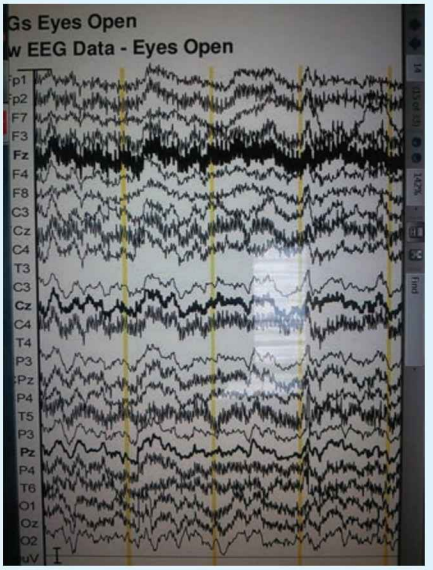
Marty has become so comfortable with travel to Panama that she comes alone with her son. "Panama was awesome. I'd love to live there. It's very safe there. The clinic is amazing, the doctors are the best I've ever met. The clinic is clean—it's not third world. Seeing the lab just blows you away. I wish more Americans knew about this. I wish that we had it here in the United States," she said.

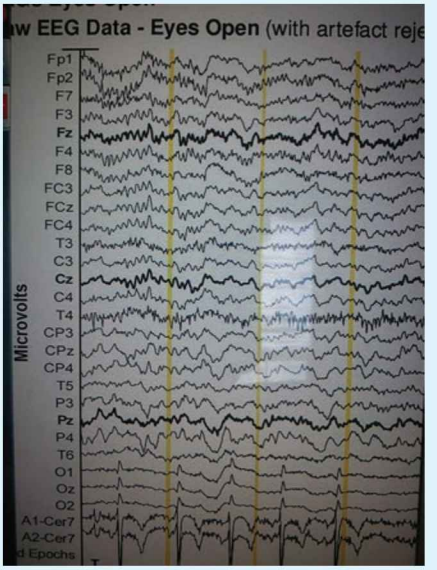
"To have someone be severely autistic and then become normal, that just doesn't happen. Every day I wake up I'm amazed by him. It's hard to believe it really happened."

Four years after his first treatment, "Ken is pretty much normal. His conversations are interesting and engaging. His mind is always thinking—in a serene, methodical way. He has a million ques-tions and loves to do schoolwork and history. He is the epitome of perfection—perfect manners, helpful to his father, full of happiness and life." His IQ has risen from 52 at age six to 98 by age 13. Not bad for a boy once diagnosed with mental retardation. "To have someone be severely autistic and then become normal, that just doesn't happen. Every day I wake up I'm amazed by him. It's hard to believe it really happened."

Ken was followed by a neurologist over the years and underwent quantitative electroencephalography (qEEG) brain scans. The results of Kenneth's qEEG scans before and after stem cell treatment were remarkably different. In 2007 his scan showed borderline seizure activity, while the scan in 2013, after six stem cell treatments, showed normal functioning in many areas of the brain.







Ethan Collins was assessed at age two and found to have a severe developmental delay. He loved to spin the wheels of his cars and propellers of his airplanes. He held socks in front of his face and repeatedly slapped. He played inappropriately with toys—he would take them apart or smash them. At age four he was diagnosed with pervasive personality disorder not otherwise specified (PDDNOS), which is on the autism spectrum, and attention-deficit hyperactivity disorder (ADHD). The psychiatrist prescribed some heavy medications, but his parents refused them.

Ethan was eventually pulled out of public school because his behavior and flight tendencies were too high of a risk. Ethan's mother Sarah happened to be the special education teacher at his school, but she quit when he changed schools. "I couldn't take care of everyone else's special needs children when I felt like I couldn't take care of my own," she said. Ethan was placed into a self-contained school for autistic children.

They began to look into stem cell treatment, and found Marty Kelly's story of Kenneth. After speaking with her, Ethan's parents decided to come down for treatment. Ethan was eight years old. "Instantly, things started to change for him," Sarah said. There was a pool at the condo they stayed in during their visit. Swimming lessons—or any sports, for that matter—had always been an issue. Ethan would become so disruptive that sports were not an option. The first two days in the pool in Panama were no different—Ethan was panicked, screaming, "I'm drowning! I'm going to die!" But on day three, he said, "I feel really good," as he slid into the pool and began to swim with no problem. "We couldn't believe the difference in him that quickly," Sarah said.

Later that week they went out to eat and expected Ethan to opt for his usual chicken nuggets and French fries, but when asked if he saw anything he wanted to try, Ethan asked for a new food. "This is a kid who would literally vomit if you

"He's doing amazingly well. He's adapting, learning how to do new things. He manages his classes, makes his own breakfasts, dresses himself—he's a normal kid."

tried to get him to eat something that wasn't in his regular diet," Sarah said. "We were so excited. We couldn't believe that he was eating something different and that it had vegetables in it."

On their way home to Arizona, Ethan was full of conversation. He even remembered the name of his teacher's dog, which says a lot considering he usually couldn't even remember his teacher's name. Once home, he visited his psychiatrist, who likened Ethan's progress to the clearing of a fogged mirror. He was amazed. "We eventually stopped seeing him because Ethan was able to come off of all five heavy medications he had been taking," Sarah said. Ethan's tics, teeth grinding, constipation, and aggression all stopped.

Ethan is now twelve and attends regular seventh-grade classes. "He's doing amazingly well. He's adapting, learning how to do new things. He manages his classes, makes his own breakfasts, dresses himself—he's a normal kid," his mom says.

Victoria's son was diagnosed with autism at 19 months of age. By the time he was nine years old, after having tried a wide array of therapies and treatments, her son hadn't made much progress. He was violent and attacking his family daily. "I had bruises and scratches all over my arms," Victoria said. Because of his explosive and dangerous behavior and the fact that they had a younger daughter in the home, his parents were faced with the heartbreaking decision to place him in a residential program for children like him, but his mother feared the consequences. "My son was very close to me. He needed to be near me at all times. His biggest rages were when I left him to go to the bathroom. My family was falling apart because of it."

Victoria had heard about stem cells from another family who told her the treatment might help her son. "I thought it was bogus at first. But I'd heard stories of remarkable improvements and I knew that we were at a crossroads. I didn't want to send my son away, but something had to change in him because he was putting my daughter at risk." When she became pregnant with her third child, Victoria decided to try stem cell treatment.

"Before stem cell therapy, my son was miserable. No test could tell me whether he was in pain, but he was angry all the time. I just wanted my son to smile."

The first four weeks after treatment, her son got worse. "At first I thought, 'What did I do?'" Stem cell treatment does not always work right away as it did for Anthony and Kenneth. Sometimes the body needs time to adjust to the changes going on inside. "At the sixth week he started getting happy, and his behaviors got better." Even his team of therapists agreed that it was the stem cells that had finally made a difference.

"If this treatment hadn't been an option, I don't know what my life would be like right now."

He started having regular bowel movements—no more fecal impaction. He slept at night like he hadn't been able to before. His learning improved. And most importantly, he stopped attacking his family. He no longer needed to be placed outside the home. "I have my happy son back, and that was all I wanted. Everything else is bonus. If this treatment hadn't been an option, I don't know what my life would be like right now."

We are currently analyzing data on a prospective analysis of a 33-case series of autism patients who were treated with umbilical cord MSCs. The patients were treated on four occasions, three months apart, with four infusions of stem cells. Data are being analyzed on the suppression of inflammatory cytokines commonly elevated in autistic patients, EEG scans, Childhood Autism Rating Scale scores, and Autism Treatment Evaluation Checklist scores. The study will be published in the next couple years, after patients have been followed for at least one year after treatment.

The Marcus Foundation has funded stem cell research at Duke University and the University of Miami for children with autism. They are

currently recruiting for their second clinical trial, a phase II clinical trial that will examine the effect of both donor and the patients' own umbilical cord stem cells in autistic children. Bernie Marcus, founder of the Marcus Foundation, believes that once the results of these clinical trials are published, parents of autistic children will push legislators to pass bills that make stem cell research available to this population of children who are in desperate need of an effective treatment. I agree with him. "I have been a real advocate for stem cells, starting with Panama, trying to get some of these things past the FDA. We're hoping to prove the point that none of this is placebo effect," said Marcus.

References

Chapter Thirteen

1. Vargas DL, Nascimbene C, Krishnan C, Zimmerman AW, Pardo CA. Neuroglial activation and neuroinflammation in the brain of patients with autism. Ann Neurol. 2005;57(1):67-81.
2. Stubbs G, Interferonemia and autism. J Autism Dev Disord. 1995;25(1):71-3.
3. Sweeten TL, Posey DJ, Shankar S, McDougle CJ. High nitric oxide production in autistic disorder: a possible role for interferon-gamma. Biol Psychiatry. 2004;55(4):434-7.
4. Ichim TE, Solano F, Glenn E, et al. Stem cell therapy for autism. J Transl Med. 2007;5:30.doi: 10.1186/1479-5876-5-30.
5. Ashwood P, Anthony A, Torrente F, Wakefield AJ. Spontaneous mucosal lymphocyte cytokine profiles in children with autism and gastrointestinal symptoms: mucosal immune activation and reduced counter regulatory interleukin-10. J Clin Immunol. 2004;24(6):664-73.
6. Okada K, Hashimoto K, Iwata Y, Nakamura K, Tsujii M, Tsuchiya KJ, et al. Decreased serum levels of transforming growth factor-beta1 in patients with autism. Prog Neuropsychopharmacol Biol Psychiatry. 2007;31(1):187-90.
7. Neuhaus E, Beauchaine TP, Bernier R. Neurobiological correlates of social functioning in autism. Clinical psychology review. 2010;30(6):733-748.doi: 10.1016/j.cpr.2010.05.007.
8. Park SY, Cervesi C, Galling B, et al. Antipsychotic use trends in youth with autism spectrum disorder and/or intellectual disability: a meta-analysis. J Am Acad Child Adolesc Psychiatry. 2016;55(6):456-468.e4. doi: 10.1016/j.jaac.2016.03.012.
9. Golnik AE and Ireland M. Complementary alternative medicine for children with autism: a physician survey. J Autism Dev Disord. 2009;39(7):996-1005.doi: 10.1007/s10803-009-0714-7.
10. Al-Ayadhi LY and Mostafa GA. Elevated serum levels of macrophage-derived chemokine and thymus and activation-regulated chemokine in autistic children. J Neuroinflammation. 2013;10:72. doi: 10.1186/1742-2094-10-72.
11. Ashwood P, Krakowiak P, Hertz-Picciotto I, Hansen R, Pessah IN, Van de Water J. Altered T cell responses in children with autism. Brain Behav Immun. 2011;25(5):840-9.doi: 10.1016/j. bbi.2010.09.002.
12. Şimşek Ş et al. Elevated levels of tissue plasminogen activator and E-selectin in male children with autism spectrum disorder. Autism Research. May 2016.
13. Tsilioni I et al. Translational psychiatry - children with autism spectrum disorders, who improved with a luteolin-containing dietary formulation, show reduced serum levels of TNF and IL-6. Translational Psychiatry. 2015;5(9):647.
14. Nikolov RN, Bearss KE, Lettinga J, et al. Gastrointestinal symptoms in a sample of children with pervasive developmental disorders. J Autism Dev Disord. 2009;39(3):405-413.doi: 10.1007/s10803- 008-0637-8.

15. Mazurek MO, Vasa RA, Kalb LG, et al. Anxiety, sensory over-responsivity, and gastrointestinal problems in children with autism spectrum disorders. J Abnorm Child Psychol. 2013;41(1):165– 176.doi: 10.1007/s10802-012-9668-x.

16. Horvath K and Perman JA. Autism and gastrointestinal symptoms. Curr Gastroenterol Rep. 2002;4(3):251-8.

17. Pramparo T, Pierce K, Lombardo MV, et al. Prediction of autism by translation and immune/ inflammation coexpressed genes in toddlers from pediatric community practices. JAMA Psychiatry. 2015;72(4):386-394.doi: 10.1001/jamapsychiatry.2014.3008.

18. Herbert MR et al. Dissociations of cerebral cortex, subcortical and cerebral white matter volumes in autistic boys. Brain. 2003;126(5):1182–1192.

19. Herbert MR. Large brains in autism: The challenge of pervasive abnormality. The Neuroscientist. 2005;11(5):417–440.

20. Kern JK et al. Relevance of Neuroinflammation and encephalitis in autism. Frontiers in Cellular Neuroscience. 2016;9.

21. Di Marco B, Bonaccorso CM, Aloisi E, D'Antoni S, Catania MV. Neuro-Inflammatory mechanisms in developmental disorders associated with intellectual disability and autism spectrum disorder: A Neuro- immune perspective. CNS & Neurological Disorders - Drug Targets. 2016;15(4):448–463.

22. Ichim, TE et al. Stem cell therapy for autism. J Transl Med, 2007. 5: p. 30.

23. Madrigal M, Rao KS, and Riordan NH. A review of therapeutic effects of mesenchymal stem cell secretions and induction of secretory modification by different culture methods. J Transl Med. 2014;12(1):260.doi: 10.1186/s12967-014-0260-8.

24. Liang J, Zhang H, Hua B, et al. Allogeneic mesenchymal stem cells transplantation in treatment of multiple sclerosis. Mult Scler. 2009;15(5):644-6.doi: 10.1177/1352458509104590.

25. Sheikh AM, Nagai A, Wakabayashi K, et al. Mesenchymal stem cell transplantation modulates neuroinflammation in focal cerebral ischemia: contribution of fractalkine and IL-5. Neurobiol Dis. 2011;41(3):717-724.doi: 10.1016/j.nbd.2010.12.009.

26. Sun L, Wang D, Liang J, et al. Umbilical cord mesenchymal stem cell transplantation in severe and refractory systemic lupus erythematosus. Arthritis Rheum. 2010;62(8):2467-75.doi: 10.1002/ art.27548.

27. Xu J, Wang D, Liu D, et al. Allogeneic mesenchymal stem cell treatment alleviates experimental and clinical Sjögren syndrome. Blood. 2012;120(15):3142-51.doi: 10.1182/blood-2011-11-391144.

28. Gesundheit B, Ashwood P, Keating A, Naor D, Melamed M, Rosenzweig JP. Therapeutic properties of mesenchymal stem cells for autism spectrum disorders. Med Hypotheses. 2015;84(3):169-77. doi: 10.1016/j.mehy.2014.12.016.

29. Lalu MM, McIntyre L, Pugliese C, et al. Safety of cell therapy with mesenchymal stromal cells (SafeCell): a systematic review and meta-analysis of clinical trials. PLoS One. 2012;7(10):e47559. doi: 10.1371/journal.pone.0047559.

30. Lv YT, Zhang Y, Liu M, et al. Transplantation of human cord blood mononuclear cells and umbilical cord-derived mesenchymal stem cells in autism. J Transl Med. 2013;11:196.doi: 10.1186/1479- 5876-11-196.

31. Sharma A, Gokulchandran N, Sane H, et al. Autologous bone marrow mononuclear cell therapy for autism: an open label proof of concept study. Stem Cells Int. 2013;2013:623875.doi: 10.1155/2013/623875.

32. Hospital Universitario; Jose Gonzalez. autologous bone marrow stem cells for children with autism spectrum disorders. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 July]. Available from: https://clinicaltrials.gov/ct2/show/NCT01740869 NLM Identifier: NCT01740869.

33. Translational Biosciences. allogeneic umbilical cord mesenchymal stem cell therapy for autism. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 July]. Available from: https://clinicaltrials.gov/ct2/show/NCT02192749 NLM Identifier: NCT02192749.

34. Sutter Health; Michael Chez, MD. Autologous cord blood stem cells for autism. In: ClinicalTrials. gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 July]. Available from: https://clinicaltrials.gov/ct2/show/NCT01638819 NLM Identifier: NCT01638819.

35. NeuroGen Brain and Spine Institute. Stem Cell Therapy in Autism Spectrum Disorders. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 July]. Available from:https://clinicaltrials.gov/ct2/show/NCT01974973 NLM Identifier: NCT01974973.

36. Ageless Regenerative Institute. Adipose Derived Stem Cell Therapy for Autism. In: ClinicalTrials. gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 July]. Available from:https://clinicaltrials.gov/ct2/show/NCT01502488 NLM Identifier: NCT01502488.

Additional References

Germain B, Eppinger MA, Mostofsky SH, DiCicco-Bloom E, Maria BL. Recent advances in understanding and managing autism spectrum disorders. J Child Neurol. 2015;30(14):p. 1887-920. doi: 10.1177/0883073815601499.

Nikolov RN, Bearss KE, Lettinga J, et al. Gastrointestinal symptoms in a sample of children with pervasive developmental disorders. J Autism Dev Disord. 2009;39(3):405-13.doi: 10.1007/s10803- 008-0637-8.

Sheikh AM, Nagai A, Wakabayashi K, et al. Mesenchymal stem cell transplantation modulates neuroinflammation in focal cerebral ischemia: contribution of fractalkine and IL-5. Neurobiol Dis. 2011;41(3):717-24.doi: 10.1016/j.nbd.2010.12.009.

Ichim TE, Solano F, Glenn E, et al. Stem cell therapy for autism. J Transl Med. 2007;5:30. doi: 10.1186/1479-5876-5-30.

Siniscalco D, Bradstreet JJ, and Antonucci N. Therapeutic role of hematopoietic stem cells in autism spectrum disorder-related inflammation. Front Immunol. 2013;4:140.doi: 10.3389/ fimmu.2013.00140.

Sharma A, Gokulchandran N, Chopra G, et al. Administration of autologous bone marrow-derived mononuclear cells in children with incurable neurological disorders and injury is safe and improves their quality of life. Cell Transplant. 2012;21 Suppl 1:S79-90. doi: 10.3727/096368912X633798.

Simberlund J, Ferretti CJ, and Hollander E. Mesenchymal stem cells in autism spectrum and neurodevelopmental disorders: pitfalls and potential promises. World J Biol Psychiatry. 2015;1-8.

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