

REPORT

ALSUntangled No. 5: Investigating the Stowe/Morales ALS Protocol

THE ALSUNTANGLED GROUP

ALSUntangled Group has just celebrated its first birthday. We currently have 168 followers on the twitter feed, and 35 tweets sent. Within our NING, we have 66 ALS clinician scientists from across five countries participating in 30 open discussions. New since the last report are open discussions about Dr. Geeta Shroff at Mediworld in India, the Perlmutter Clinic in Naples Florida, and Brainstorm-Cell. We have four publications on five different alternative and off-label therapies. We just received our first monetary donation from the Virginia Gentlemen's Foundation, which will allow us to create our own website, and fund travel to more of the for-profit clinics offering alternative and off-label therapies to patients with ALS.

Stowe/Morales Protocol

Recently we were invited to work with the investigative team at 60 Minutes to investigate the Stowe/Morales Protocol for ALS. 60 Minutes is an American news program on the television network CBS; it is highly respected, having run for more than 40 years and garnered 78 Emmy Awards. The 60 Minutes version of this investigation was recently shown on television and now appears on their website (1). Our version follows. ALSUntangled had the following data available to us for our investigation: a website (2), written protocols, transcripts of a phone conversation this group had with a patient and a letter they sent to a patient (supplied by 60 Minutes investigators). We looked for research publications by Drs. Stowe or Morales related to this Protocol and found none. We looked within our clinics to determine if any of our patients had ever been exposed to this protocol; we were unable to find any of our patients that had.

Rationale

This rationale behind the Stowe/Morales ALS Protocol is the assumption that MS, Parkinson's disease and ALS have common pathophysiologies

involving 'infections and toxins'. This rationale appears to be an offshoot of the one provided on the Stowe Foundation's website for their diabetes protocol. With regard to diabetes, they refer to it as the 'PITTS syndrome'. 'P' stands for poor nutrition. This leads to an evaluation where recommendations are made for nutritional deficiencies. 'I' stands for infection. This is due to the theory that all chronic illness is due to infection of some sort – you will need laboratories to determine the infection agent and once isolated it can be grown up and used to create a vaccination that is individualized. 'T' stands for toxins. Once toxins are identified then therapies can be targeted to the individual. They claim that they manipulate the energy fields to allow optimal biochemical reactions and removal of toxins, i.e. change the ionic binding of the toxin. The next 'T' stands for trauma, which can be either physical or emotional. The treatment of physical trauma may require surgical intervention to realign the body – or a simple chiropractic adjustment to help the energy meridians of the body to flow freely. For emotional trauma, they use something called a 'Genie machine'. 'S' stands for stress, which is said to be an energy disturbance. They claim they can detect certain energy disturbances because different types of stress influence different organs. Stress patterns related to finance disturb certain areas of the central nervous system, while stress patterns associated with interpersonal relationships disturb a different part. Since the brain is in communication through the spine, looking at energy disturbances along the spine gives clues to the stress pattern and then it can be corrected. Once the 'infections and toxins' have been removed (or treatment for PITTS syndrome is completed), patients can receive stem cells to regenerate the damaged parts of their bodies. With regard to ALS, the stem cells are purported to become motor neurons. The authors of the Stowe/Morales Protocol do not provide references to support their hypotheses.

ALSUntangled is unaware of any data supporting the idea that ALS, MS, Parkinson's disease and

diabetes are caused by common infections or toxins. HIV is the only infection ever shown to cause an ALS-like disease, and this is exceedingly rare (3). No toxic agent has ever reliably been documented in patients with ALS. Thus, the rationale for the Stowe/Morales ALS Protocol does not appear sound or even reasonable to us.

Protocol

The Stowe/Morales ALS Protocol is not being offered as a research study, but rather as a therapy. In a conversation with a prospective patient, Dr. Stowe compares his protocol to the FDA approved stem cell study being run through the University of Michigan and Emory (4). However, the Stowe/Morales ALS Protocol does not have the scientific rigor of the Michigan/Emory. The Stowe/Morales ALS Protocol is not FDA approved, appears to have no informed consent process, appears to have no inclusion or exclusion criteria (nor even any clear validation of presenting diagnoses), utilizes a large number of extra supplements of unproven safety or efficacy prior to stem cell transplant, uses completely different stem cells, injects the cells into a different place in the body, and apparently has no validated safety or efficacy outcome measures. There are substantial fees charged for participating in the Stowe/Morales ALS Protocol (approximately \$150,000 per course). Patients who participate in FDA approved stem cells studies are not charged anything to participate

Pre-stem cell part of the protocol

Many of the items in this part of the protocol have mysterious names; it is unclear what they represent. These include ‘immune regulation vaccine’, ‘patient specific transfer factors’, ‘biologic response modifiers’, ‘immune therapy supplements’, ‘peptides compounded in New Mexico’, ‘energy medicines’, ‘micro-current devices’, ‘therapeutic cold lasers’, ‘pulsed magnetic therapy’, ‘Avacen for body temperature control’, ‘Applied BioLogics program to enhance the ability of the stem cells to grow new tissue in the body capable of restoring function to muscle control’ and ‘comprehensive immune therapy program’.

A review of the literature finds no evidence that ALS is due to heavy metal toxicity; therefore, the use of ‘detoxification and purification-clathrating agents’ makes no sense to us.

Three of the supplements given in the pre-stem cell part of the Stowe/Morales ALS Protocol were previously studied in patients with ALS and shown to have no benefit (5–7). These include CoQ10, glutathione and anti-oxidants. Based on these negative trials, ALSUntangled does not support giving these to patients with ALS.

Based upon current theories of ALS pathogenesis, ALSUntangled can see no reason that testosterone, vitamin D or thyroid supplements would be useful in people with normal testosterone, vitamin D and thyroid levels. Excessive levels of hormones can be harmful. Furthermore, ALS Untangled identifies no reasons that the suggested dietary changes would be useful. Dietary suggestions that cause weight loss to patients with ALS may be harmful.

Stem cell part of the protocol

The exact stem cell protocol being used is unclear. In a conversation with a prospective patient, Dr. Stowe at one point mentions using umbilical cells. Later, mention is made of using both umbilical cells and bone marrow cells, and at another point “stem cells you get from fat” are being proposed. It is not clear how the stem cells are being isolated or matched. It is not clear that the stem cells are being pre-differentiated in any way; without pre-differentiation, there is a risk of stem cells becoming tumors. The stem cells are being injected into the spinal fluid. It has not been demonstrated that stem cells injected into humans in this way can engraft into the central nervous system, differentiate into a specific cell type such as a motor neuron or even survive at all. Even if they can differentiate into motor neurons, there is no evidence in humans that these new motor neurons would be able to send processes outside the spinal cord, find any muscle, and functionally re-innervate the muscle.

Outcomes, risks and benefits

No specific validated outcome measures appear to be used in the Stowe/Morales ALS Protocol.

There does not appear to be any reasonable tracking of adverse events, or any reasonable discussion of potential risks. In a letter to a prospective patient, Dr. Morales writes “We have been treating patients for over eight years with a total of well over 1000 patients with the blessings of only having positive results and no negative side-effects.” ALSUntangled cannot understand how this is possible. Even simple bone marrow biopsies and lumbar punctures alone have side-effects.

Finally, ALSUntangled believes that the reports of efficacy being relayed to prospective patients looking at the Stowe/Morales ALS Protocol are impossibly optimistic. As mentioned above, there is no proof that stem cells derived from cord blood or bone marrow can be injected into the spinal fluid of humans and even survive, much less form living motor neurons. Even this would be a far cry from forming motor neurons that can re-connect with skeletal muscle and significantly improve strength. However, Dr. Stowe claims “We’ve had.... a number

of.... ALS, you know, patients..... that we got out of their wheelchairs.” When a prospective patient asks Dr. Stowe about the time-course over which he might “expect some restoration of my lost strength and lost muscles”, he is told “three, four weeks”. Even if these types of stem cells delivered in this way could miraculously do what is being described as fact, the time-course being promised (“three, four weeks”) is not physiologically possible. New neurons would be expected to grow at approximately 1 mm per day. Finally, Dr. Stowe mentions “If we were a major pharmaceutical drug company.....we'd be talking about all of our research and getting Nobel Prizes.” It is difficult to understand why anyone with a treatment that was this dramatically effective against these terrible diseases would not want to present it publicly and win all the accolades, financial and otherwise, that would come with it.

Conclusions

In summary, ALSUntangled strongly recommends that patients with ALS avoid the Stowe/Morales ALS Protocol. The rationale for this exorbitantly expensive protocol is unsound. The specific treatments being used range from mysterious, to already disproven, to potentially harmful. No valid outcome measures are being followed and the discussion of safety and efficacy taking place between sellers and potential patients considering this is impossibly optimistic.

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Note: this paper represents a consensus of those weighing in. The opinions expressed in this paper are not necessarily shared by every investigator in this group.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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