



## ALSUntangled Update 4: Investigating the XCell-Center

### THE ALSUNTANGLED GROUP

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## REPORT

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### Overview

Now in existence for 11 months, ALS Untangled (1) has 137 twitter followers, 64 ALS clinician-scientists from across four countries participating in its investigations, three published investigations (2–4) and 26 active investigations. New active investigations underway since our last publication include Zhu Ming's Protocol at Huaihua Red Cross Hospital, the Beike Clinic, the Case of Dr. Martz, Stem Cells via TCA Cellular, the Marty Murray Protocol and the Regenocyte Clinic.

At the request of patients with ALS, we recently reviewed the XCell-Center. Data used for this review included the XCell-Center's website (5), and a small number of our own patients' experiences there.

### Website review

The XCell-Center is a private stem cell clinic with locations in Dusseldorf and Cologne, Germany. It reports having a Scientific and Medical Advisory Board of “experts from all over the world”. Following this declaration, three names are mentioned as being on this board, one neurosurgeon from Germany and two neurosurgeons from the USA. None of these is a recognized member of the ALS community of clinician-scientists.

In addition to advertising its version of stem cell transplants to patients with ALS, the XCell-Center also advertises it to patients with Alzheimer's disease, autism, cardiovascular disease, cerebral palsy, diabetes mellitus types 1 and 2, failed back syndrome, macular degeneration, multiple sclerosis, osteoarthritis, Parkinson's disease, spinal cord injuries and stroke. From reading their case reports, they have even given it to a patient with “non-diagnosable degenerative neurologic disease”. It is not clear how any of these presenting diagnoses are validated. No other inclusion or exclusion criteria are specified.

The authors of the XCell-Center website state that they do not have a clear understanding of how their stem cells participate in healing, but they believe it is either by replacing damaged cells or secreting

something that stimulates the healing of damaged tissue. Despite this lack of rationale, the XCell-Center protocol is being offered to patients with ALS as a treatment option and not a research study.

The XCell-Center protocol for patients with ALS starts with a bone marrow biopsy. The bone marrow aspirate is tested for infections, and exposed to a “chromatographical procedure” to separate stem cells. If there are “enough vital stem cells” (which they claim to be “more than two million CD 34+ cells with over 80 percent vitality”), then the stem cell solution is approved and stored in liquid nitrogen. The next day, the stem cells are injected into either venous blood or cerebrospinal fluid (the website is contradictory in different areas on this). One to three days later patients return home. Some are apparently contacted later for subjective reports on how they are doing. The cost of this is 7500 euros for each implantation via lumbar puncture. There are other potential costs involved, including travel, hotels, meals, physician fees, anaesthesia, and additional bone marrow implantations (if necessary).

There does not appear to be an overall informed consent for this protocol, although the website does show reasonable informed consent forms for bone marrow biopsy and lumbar puncture. These individual consent forms appropriately list the risks of these procedures.

In terms of results, since January 2007 more than 2400 patients have apparently undergone stem cell transplants at the XCell-Center. If true, it is remarkable how few data are actually reported on the website. There are no data on the website showing that the XCell-Center stem cell transplants even survive in patients with ALS. There does not appear to be any systematic follow-up, nor any use of validated ALS outcome measures. From a safety standpoint, there is a report on 870 patients undergoing the lumbar puncture portion of the protocol; the incidence of post-lumbar puncture complications in this series appears consistent with other published series. It is unclear how many of these 870 patients had ALS. The results of a small pilot study of patients with ALS

are also shown. No methodological details are given for this study, nor can ALSUntangled recall seeing this presented at a scientific meeting. Our best guess as to what took place in this apparently non-randomized, non-blinded, uncontrolled pilot study is that 53 patients with ALS were contacted, some time between one and six months after their transplants, for a subjective report on their progress. Sixteen of 53 patients reported no positive changes, 17 “perceived deterioration” and the remaining 20 reported some degree of improvement in something. (Mobility, breathing, swallowing, speech, strength, spasms and sleep are all variously reported but it is unclear whether there were common improvements, or whether each patient experienced something different.) The website's conclusion from this pilot study is that “40% of the ALS patients treated with stem cells at the XCell-Center showed improvement”. No mention is made of the limitations of this pilot study including the small number, the very short latency follow-up, or the very likely presence of a placebo effect here. When reporting on the safety of those in this small pilot, the website states “it is believed that the treatment has not adversely affected the patients”.

### Patient experience

ALSUntangled is aware of three patients with ALS under our care who have had treatment at the XCell-Center. The first patient was followed for 10 months after this treatment. She reported improved cramps and muscle strength, but by manual muscle testing she clearly worsened. The second patient was followed for nine months after this treatment and deteriorated both subjectively and objectively. The third was followed for three months and had no change in progression rate.

### Conclusion

While we applaud the use of informed consent for portions of the XCell-Center protocol, and the presentation of pilot efficacy and safety data, in our opinion many worrisome questions and problems remain. From a rationale standpoint, we feel it is unlikely that all the diverse diseases (some without a name at all) being treated at the XCell-Center would respond to the same type of treatment. Nothing useful can be concluded from the flawed ALS pilot data that are presented; the positive effects reported are very likely nothing more than a placebo effect as seen in the first of our patients above. Regardless of whether the XCell product results in new motor neurons or promotes sprouting of existing ones, patients with ALS would not be expected to have improved motor function just one or even a few months after treatment as is being claimed. In our opinion, these misleading pilot data should be removed from the website or at least qualified with appropriate disclaimers.

We hope the XCell group will present all their ALS data for peer review, including evidence that their cells are surviving, as well as objective clinical outcome measures over a reasonable length of follow-up. This would be a useful first step toward planning what is ultimately necessary to demonstrate the safety and efficacy of this protocol – a randomized, blinded, controlled trial. Until this is completed, we do not condone the XCell Center's protocol for patients with ALS.

### Group membership

The ALSUntangled Group currently consists of the following members: Richard Bedlack, Orla Hardiman, Nazem Atassi, Dallas Forsheiw, John Ravits, Robin Conwit, Carlayne Jackson, Alex Sherman, Kate Dalton, Katherine Tindall, Ginna Gonzalez, Janice Robertson, Larry Phillips, Michael Benatar, Eric Sorenson, Christen Shoesmith, Steven Nash, Nicholas Marigakis, Dan Moore, James Caress, Kevin Boylan, Carmel Armon, Megan Grosso, Bonnie Gerecke, Jim Wymer, Alberto Ascherio, Bjorn Oskarsson, Alberto Ascherio, Robert Bowser, Vivian Drory, Jeremy Shefner, Terry Heiman-Patterson, Noah Lechtzin, Melanie Leitner, Robert Miller, Hiroshi Mitsumoto, Todd Levine, James Russell, Khema Sharma, David Saperstein, Leo McClusky, Daniel MacGowan, Jonathan Licht, Ashok Verma, Michael Strong, Catherine Lomen-Hoerth, Rup Tandan, Michael Rivner, Lisa Krivickas, Steve Kolb, Meraida Polak, Stacy Rudnicki, Pamela Kittrell, Muddasir Quereshi, George Sachs, Gary Pattee, Tahseen Mozaffar, Michael Weiss, John Kissel, Merit Cudkowicz, Jonathan Goldstein, Jeffrey Rothstein, Dan Pastula.

**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.

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