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1. Indian Stem Cell Trial to Broaden Diabetic Foot Inclusion Criteria

16th Sept, 2009

Fortis Healthcare, one of India's leading private hospital groups, has announced it will broaden inclusion criteria for its upcoming diabetic foot clinical trial. The study will use stem cells derived from peripheral blood to treat critical limb ischemia (diabetic foot). Current treatment of diabetic foot ulcers involves intensive wound management, risk reduction and lengthy rehabilitation. The current treatments available for diabetic foot are both expensive and labor intensive.

The study will determine whether stem cells can be effectively used to treat and facilitate faster recovery for this condition. The trial is being sponsored by Beike Biotech India Private Company Limited. Diabetic foot disease is the most common serious complication of diabetes and can lead to recurring wounds, frequently in the form of foot ulcers. The nerve damage and impaired blood circulation found in diabetics play a key role in ulcer formation. In severe cases, the affected limb must be partially or completely amputated.

While the study's design was formally approved by the Indian Council of Medical Research (ICMR) in June 2009, the original inclusion criteria have proven prohibitively narrow, limiting subject enrollment and delaying the start of the study.

Dr. Anoop Misra, director of the trial, explained that the inclusion criteria were based on pilot studies conducted in China. "Out of over 150 patients screened, only one subject fit our original criteria." He went on to suggest that diabetic foot disease experienced in a clinical setting may have differing characteristics in India and China. Fortis notified the Indian Council of Medical Research of the need to revise the inclusion criteria, and it can now move forward. The trial was scheduled to start in July and to include a total of 36 patients, of whom 12 are to be randomly selected to receive stem cell treatment. The trial's focus is on healing diabetic foot ulcers with stem cells. If effective, the treatment should improve blood perfusion in the ischemic area of the lower limb. This improvement will be assessed by measuring the change in transcutaneous partial pressure of oxygen (TCpO2), and will also involve NMR angiography of the local vessels, assessment of ulcer healing, pain relief, limb salvage, and the ABI index. Diabetic foot disease is a serious issue in India. A successful trial will have significant implications for future treatment of the condition.

"Many of our stem cell treatments to date have focused on rare and otherwise incurable conditions. This study marks an important step in verifying the applicability of stem cell therapies to more commonly occurring, serious pathologies," said Dr. Sean Hu, CEO and Chairman of Shenzhen Beike Biotechnologies Co. Ltd., regarding the implications of the study. Hu continued, "The Chinese pilot trial yielded promising results which is encouraging for everyone who deals with patients affected by diabetic foot disease or related ischemic complications. As with all scientific advancements,

it is important to demonstrate that it is effective and reproducible in the broader international setting. The replication of this study in India will both underline the effectiveness of the treatment protocol we have developed and demonstrate that it can be applied by the international medical community." The preceding study in China produced promising results, increasing blood perfusion, markedly reducing

ulceration, and raising TCpO2 levels. In some cases patients regained function in limbs that had been candidates for amputation.

Lalit Jaiswal, CEO of Beike Biotech India Private Company Limited, added, "China has been at the forefront of stem cell technology for several years, and this study is a logical next step for the company. It is exciting that we will now be able to examine the potential of peripheral blood-derived stem cells to induce neovascularization," Lalit continued, "The clinical value of bone marrow stem cells has been known for years, and we hear about fetal and embryonic stem cells in the news every day. In this study, though, we are processing a patient's own blood to isolate stem cells and then using these stem cells to treat their diabetic foot ulcers and circulatory problems. When this trial is over we will have confirmed whether a diabetic patient's own peripheral blood can be used to induce the growth of new blood vessels in their damaged tissue."

The clinical trial is officially titled, "A Randomized, Controlled, Parallel Design, Safety and Efficacy Study of Granulocyte Colony Stimulating Factor Mobilized Autologous Peripheral Blood Mononuclear Cell Therapy in Subjects With Diabetic Limb Ischemia." India's Council of Medical Research approved the study after verifying that it met all associated criteria in terms of design and controls as well as following ethical and safety standards.

"The large number of people who applied to enroll in this study confirms that there is strong demand for this therapy and a need to augment current treatment methods. However, to enroll enough subjects for a successful study we have determined that we must broaden the inclusion criteria and reapply to ICMR. Now that we have notified the ICMR we will restart the trial in October," said Dr. Anoop Misra.

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Source: Economic Times

2. A denture-free world: NSU researchers are using adult stem cells to grow replacement teeth

September 13th, 2009

Legend has it that George Washington had a mouth full of dentures that made him so uncomfortable, he decided to forgo his second inaugural address.

Washington regretted not being able to keep his natural teeth. Many people think his dentures were made of wood, but they were actually made of animal bone, lead and ivory.

Eating, smiling and talking were painful for our first president. In later life, he could only eat soft foods. Washington's dental discomfort was far from unique more than 200 years ago. Unfortunately, 45 million Americans still have problems with their dentures today.

The ideal solution to diseased, damaged and missing teeth is to regenerate new and healthy natural teeth. Clone them, if you will.

Don't believe it? Sounds too sci-fi?

Not at all. Nova Southeastern University's dental researchers at the College of Dental Medicine are growing and harvesting human dental stem cells in the laboratory.

A 2009 NSU survey of dentists around the nation revealed that more than half thought that they would be using stem cell and tissue engineering therapies on their patients within the next decade. An overwhelming 96 percent of dentists believe the ability to regenerate and replace teeth and dental tissues is the future ofdentistry, according to the survey.

The practical application of NSU's research is for replacement teeth and dental tissues to be grown in the lab and implanted into patients. Having "real" replacement teeth will allow patients to better experience normal dental sensations, such as taste. Their teeth will have the ability to function, grow and develop as normal healthy teeth.

The goal of NSU's research is to ultimately put an end to the fear of millions of Americans, who will no longer have to worry about a lack of teeth, dental pain, dental disease and using dentures.
How it's done?

The key to regenerating teeth and other body tissues is the use of adult stem cells. These are the building blocks of life. Stem cell therapies are inevitable and controversial. At some point in the future, however, dental stem cell treatments will be bringing a smile to the faces of millions of dental patients. **T**he cells normally grow in flat layers of single cells in Petri dishes. To get them to form a 3-D tissue structure, researchers seed the cells on tissue engineering scaffolds made from the same polymer material as bio-resorbable surgical sutures.

The scaffolds function like those you see around buildings under construction. They provide mechanical support and control the size and shape of a tissue. Once the stem cells are seeded on the scaffolds, researchers add growth factors to signal to the stem cells what type of tissue to grow. The combination of dental stem cells, tissue engineering scaffolds and growth factors allows researchers to engineer new tooth tissues. NSU scientists are working, similar to other research labs, to create fully functional replacement teeth.

NSU College of Dental Medicine has research grants worth $1.7 million from sources such as the National Institutes of Health to fund its dental stem cell research. That's not a lot of money, considering the advantages and benefits this research could provide. The NSU college is recognized internationally as a leader in the field of tooth regeneration, so you can be sure the money is being spent on top-notch science and research.

How soon?

Dental researchers have been successful at regenerating teeth in the laboratory and in animals. They have developed a stem cell therapy for growing new teeth following root canal treatment, and also for replanting teeth that have been knocked out of the mouth. In NSU's technique for regenerating teeth, the preclinical trial subjects were able to eat and chew normally.

No current studies have examined the ability of animals to eat using completely regenerated teeth because no one has yet regenerated all the teeth in an animal; we are still working toward that goal. In NSU's technique, which is yet to be published and patented, the soft tissue, or pulp, inside teeth was removed and regenerated. The monkey subjects were able to use their teeth normally to eat and chew. NSU dental students are busy working on projects to grow healthy teeth, nerves, blood vessels, bone and gum. Once researchers have completed FDA-approved clinical trials, their pioneering discovery will be available to patients.

The mainstream regeneration of teeth and other tissues from stem cells for humans will become reality in about a decade to 50 years. We can speed up the introduction of dental stem cell therapies if more funds are invested in the research needed to evaluate its effectiveness and safety to U.S. Food and Drug Administration standards.

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Source: Sun Sentinal

3. Jaslok Hospital Performs World's First Stem Cell Transplant on PD Patient

15th Sept, 2009

The first patient was suffering from advanced PD for the past six years

Mumbai-based Jaslok Hospital & Research Centre announced its first successful treatment of Parkinson's Disease (PD) using stem cells. Earlier this year, Jaslok Hospital had launched a revolutionary Mesenchymal Stem Cell project along with the regenerative medicine group of Reliance

Life Sciences, on World Parkinson's Day. The first patient to undergo the treatment was 54-year-old Bhanwarlal Jain suffering from advanced PD for the past six years.

PD is a degenerative disease of the brain (central nervous system) that often impairs motor skills, speech, and other possible functions. The prevalence of this disease is 8-22/10,000. As the disease progresses, medicines become less effective and cause intolerable side effects.

Presently, all the therapies for this disease only control the disease symptoms. Neural transplantation is the only form of treatment which can actually restore normal function. Stem cells transplantation if successful would prove to be a great boon for patients suffering from this disease.

Said Dr Paresh Doshi, HOD, Department of Stereotactic and Functional Neurosurgery, Jaslok Hospital, "The patient was suffering from PD for past six years. Despite taking large doses of medicine, he could independently function for only a few hours in the day and rest of the period was spent in bed or in an incapacitated manner. Surgical treatment was the only option."

The stem cells that were used were derived from the patient's own bone marrow. They were then grown and processed at the state - of-the-art cGMP complaint stem cell processing facility of Reliance Life Sciences at Navi Mumbai. Once processed, they were brought back to Jaslok Hospital where they were implanted in the patient's brain by stereotactic surgery.

The patient is required to remain awake during this surgery. Under the influence of local anaesthesia, two burr holes are made in the head through which microscopic amounts of autologus mesenchymal stem cells are injected. As these cells are from the patient's own bone marrow there is no potential of rejection, and side effects are also negated as they can multiply only for a limited time.

Jaslok Hospital and Reliance Life Sciences have partnered together to perform 10 such cases, the results of which, will be evaluated over a period of three years.

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Source: Express Healthcare

4. Indian docs cure thalassaemia using stem cells

17th Sept, 2009

When others of her age played with dolls, eight-year-old Thamirabharani was taking blood transfusions.

Born with thalassaemia, she has, however, found hope. She was detected with the disease when she was a year and a half and has been undergoing regular blood transfusions since.

Haematologist Revathy Raj and his team from Apollo Gleneagles hospital in Chennai gave a new lease of life to the little girl from Coimbatore through stem cell transplantation. Doctors said she is now fully cured and has not needed a single transfusion since March.

Doctors claimed this is the first success story in India using the stem cells from the umbilical cord blood of a sibling.

When her father Senthil Kumar, a carpenter, came to know of stem cell transfusion and Life Cell and its process of banking stem cells from umbilical cord blood, they decided to have another child.

When Thamirabharani was two years old, her mother conceived again but the foetus was also diagnosed with Thalassae-mia. They had it terminated and tried again.

During the second attempt, doctors found the foetus was a Thalassaemia carrier but not affected by it. They collected the blood from the umbilical cord, cultivated the stem cells during delivery of the baby boy and asked Life Cell to preserve it for a year.

In March, Raj and his team started working on the transplantation process.

“The first step was to destroy all the existing bone marrow cells using chemotherapy. Next came transplanting stem cells from the donor,” said Raj

Source: Hindustan Times

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5. Science Awards Go to Adult Stem-Cell Researchers

16th Sept, 2009

Dr. John Gurdon, a developmental biologist from Oxford University, and Dr. Shinya Yamanaka, a physician and researcher at Kyoto University, have been chosen to receive the prestigious Albert Lasker Basic Medical Research Award for their work with Induced Pluripotent Stem (iPS) cells.

iPS cells are embryonic-like cells that can become specialized cell types without destroying a human embryo.

In a promotional video from the Lasker Institute, Yamanaka said he's excited about the future of the research.

"I expect some diseases like heart disease, heart failure, and some retinal diseases," he said, "may be a good candidate" (for therapies using this research).

Gurdon and Yamanaka will split the $250,000 cash prize and receive their awards in New York on Oct. 2.

Source: Citizen Link

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