

World first in-human stem cell trial begins in Glasgow

November 16 2010

The first patient has been treated with stem cell therapy in a ground-breaking UK clinical trial led by the University of Glasgow.

The PISCES study, Pilot Investigation of Stem Cells in [Stroke](#), is the world's first fully regulated clinical trial of a neural stem cell therapy for disabled stroke patients.

According to Professor Keith Muir, Principal Investigator for the trial, the patient underwent the successful surgical procedure at Glasgow's Southern General Hospital and has now been discharged. The patient will be monitored closely for two years, with longer term follow-up procedures in place thereafter.

Prof Muir, Sinapse Chair of Clinical Imaging, from the University of Glasgow's Institute of Neuroscience and Psychology, said: "We are pleased that the first patient in the PISCES trial has undergone surgery successfully.

"Stroke is a common and serious condition that leaves a large number of people with significant disability. In this trial we are seeking to establish the safety and feasibility of stem cell implantation, which will require careful follow-up of the patients who take part.

"We hope that in future it will lead on to larger studies to determine the effects of stem cells on the disabilities that result from stroke."

The trial, being carried out with ReNeuron Group plc*, uses expanded neural [stem cells](#), which are the basis of Reneuron's ReN001 [stem cell therapy](#) for stroke patients.

The PISCES study will test the safety of ReN001 in ischaemic stroke patients at a range of cell doses, but a number of other measurements of its impact will also be evaluated over the course of the trial.

The ReN001 cells were administered by direct injection into the affected region of the brain in a routine surgical procedure.

The PISCES trial was given approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) in January 2009.

Ischaemic stroke is the most common form of the condition and is caused by a blockage of blood flow in the brain as opposed to a haemorrhagic or bleeding stroke.

Stroke is the third largest cause of death and the single largest cause of adult disability in the developed world.

ReNeuron is the first company to have received regulatory approval for any stem cell-based clinical trial in the UK.

The nature of the procedure and the characteristics of the ReN001 cells mean that the patients taking part in the trial will not need immunosuppression following treatment, thus eliminating the safety risks typically associated with immunosuppression regimens.

Michael Hunt, Chief Executive Officer of ReNeuron, said: “The initiation of the PISCES clinical trial is a major and hard-won milestone for ReNeuron and a significant milestone in the development of therapies to address the severely disabling effects of ischaemic stroke.

“We are delighted to be working with Professor Keith Muir and his team at one of Europe’s pre-eminent stroke treatment centres and, in so doing, helping to promote the uptake of clinical innovation in the NHS system. Our thanks and best wishes go to the first patient and his family for their participation in this important and ground-breaking clinical trial. ”

Provided by University of Glasgow

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