Fetal derived stem cells for Parkinson's disease

Submission date	Recruitment status
23/04/2016	No longer recruiting
Registration date 04/05/2016	Overall study status Completed
Last Edited	Condition category
08/08/2019	Nervous System Diseases

[] Prospectively registered

[] Protocol

- [] Statistical analysis plan
- [X] Results
- [] Individual participant data

Plain English summary of protocol

Background and study aims

Parkinson's disease (PD) is a chronic condition where nerve cells in a small part of the brain called the substantia nigra become damaged and die. The nerve cells in this region send signals that controls the muscles of the body. Dopamine is the main neurotransmitter produced by these nerve cells. As more of these cells die, the amount of dopamine produced also falls. Over time, the lack of nerve cells and low levels of dopamine affects how well the person affected can control their muscles. The most common symptoms of the condition are slowness of movement, muscle stiffness and shaking (tremors). Although temporarily effective, current treatments fail to control symptoms and stop the disease progressing. The aim of this study was to test the safety and possible benefits of a novel strategy based on grafting human fetal brain stem cells (hfSCs) I the hope that they help address both dopamine and non-dopamine aspects of the disease.

Who can participate? Patients with moderate to severe Parkinson's disease.

What does the study involve?

Participants are first temporarily immunosuppressed with the drug cyclosporine. This is to make sure that they don't reject the stem cells. The cells are then injected into a part of the brain called the dorsal putamina. All participants are then followed up for a year to see if any side effects or complications arise and whether their symptoms improve.

What are the possible benefits and risks of participating? Benefits may include an improvement in PD symptoms. Potential risks include bleeding in the brain, brain swelling and immune rejection of the cells.

Where is the study run from? Angeles Pedregal Hospital (Mexico)

When is the study starting and how long is it expected to run for? February 2011 to August 2018

Who is funding the study? Celavie Biosciences Who is the main contact? Professor Ignacio Madrazo imadrazon@parkinsonmx.com

Contact information

Type(s) Scientific

Contact name Prof Ignacio Madrazo

ORCID ID http://orcid.org/0000-0002-1181-3029

Contact details Camino a Santa Teresa 1055-474 Mexico City Mexico 10700 52555684319 imadrazon@parkinsonmx.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers CMN2012-027

Study information

Scientific Title

Undifferentiated human fetal brain-derived stem cells grafted into putamina of parkinsonian patients is safe and moderately effective: a phase I clinical trial.

Study objectives

If undifferentiated human fetal brain-derived stem cells (hfSC) are transplanted in the putamina, then patients will Parkinson's Disease will not suffer harm and will decrease their disease.

Ethics approval required Old ethics approval format

Ethics approval(s)

1. Federal Commission for Prevention of Sanitary Risks (Comisión Federal para la Prevensión de Riesgos Sanitarios), 12/02/2014, ref: CMN2012-027

2. Research Committee and Research Ethics Operadora Hospital (Comité de de Investigación y Ética en Investigación de Operadora de Hospitales Ángeles S.A. de C.V), 01/08/2014

Study design

Longitudinal, prospective, interventional, uncontrolled study

Primary study design Interventional

Secondary study design

Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Parkinson's Disease

Interventions

Stereotactical transplant of stem cells into both putamina. One million million stem cells were deposited in two areas (anterior and posterior) of both putamina. All of this is by one trephine in the coronal suture.

The patients were protected 24 hours before surgery with IV antibiotics, and a day before started with cyclosporine and indometacine which lasted for one month in the first drug and two months in the second. After surgery, they were transferred to the ICU for 24 hours and finally after a post-op MRI control, sent home.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Safety of transplantation of cells, measured by recording side effects or complications arising after surgery.

2. Degree of motor improvement, measured using the unified Parkinson's disease rating scale (UPDRS) score

Secondary outcome measures

1. Cognitive performance, measured using the mini–mental state examination (MMSE) score at baseline and at 1 year follow-up

2. Uptake patterns of DTBZ, FDOPA and RAC

Overall study start date 18/02/2011

Completion date 25/08/2018

Eligibility

Key inclusion criteria Healthy patient with Parkinson's Disease

Participant type(s) Patient

Age group All

Sex Both

Target number of participants 8

Total final enrolment 8

Key exclusion criteria 1. Pregnancy 2. Secondary pathology

Date of first enrolment 01/06/2011

Date of final enrolment 14/11/2012

Locations

Countries of recruitment Mexico

Study participating centre Angeles Pedregal Hospital Camino a Santa Teresa 1055 Mexico City Mexico 10700

Sponsor information

Organisation Celavie Biosciences

Sponsor details 2360 Eastman Ave Ste 101 Oxnard, California United States of America 93030

Sponsor type Industry

ROR https://ror.org/059xdv132

Funder(s)

Funder type Industry

Funder Name Celavie Biosciences

Results and Publications

Publication and dissemination plan Planned publication in a high-impact peer-reviewed journal.

Intention to publish date 31/12/2018

Individual participant data (IPD) sharing plan We intend to share participant level data in Dryad, however the details are still being decided.

IPD sharing plan summary Stored in repository

Study outputs Output type

Details Date created

Date added

Peer reviewed?

Patient-facing?

Basic results		01/10/2018	01/10/2018	No	No
<u>Basic results</u>		04/10/2018	04/10/2018	No	No
<u>Results article</u>	results	01/03/2019	08/08/2019	Yes	No