ISRCTN39104513 https://doi.org/10.1186/ISRCTN39104513

Fetal derived stem cells for Parkinson's disease

Submission date
23/04/2016

Recruitment status
No longer recruiting

Registration date
04/05/2016

Overall study status
Completed

Last Edited
08/08/2019

Condition category
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
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Contact information

Type(s)
Scientific

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