

Fetal derived stem cells for Parkinson's disease

Submission date 23/04/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/05/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/08/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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) in 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

Contact name
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Additional identifiers

Protocol serial number
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 Prevención 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

Primary study design
Interventional

Study design

Longitudinal, prospective, interventional, uncontrolled study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

25/08/2018

Eligibility**Key inclusion criteria**

Healthy patient with Parkinson's Disease

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

All

Sex

All

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

ROR

<https://ror.org/059xdv132>

Funder(s)**Funder type**

Industry

Funder Name

Results and Publications

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