Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

DOPASON project: The Assessment of Safety and Feasibility of Intra-Striatal Transplantation of Human Embryonic stem cell-derived Dopaminergic Progenitors (DopaCell) in Parkinson’s disease: A Multicenter Phase I Clinical Trial

Protocol summary

Study aim
Determining the safety and feasibility of intracerebral transplantation of DupaCell in patients with PD

Design
Single-arm, non-blinded and non-randomized, phase 1, multicenter clinical trial on 4 patients.

Settings and conduct
This study will be conducted over 24 months in two hospitals. After obtaining informed consent, four patients will be included in the study and will undergo one round of surgery. During the surgery, a cell suspension transplant will be performed in the striatum of each brain hemisphere. Patients will be followed during hospitalization and 1, 3, 6, 9 and 12 months post-op.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age of 30 to 70 years; Diagnosis of Parkinson's disease; Duration of 5 years from the diagnosis; under medical treatment; Hoehn-Yahr scale of at least 3 in the Off-period and a maximum less than 3 in the On-period; Exclusion criteria: underlying systemic disease; Symptomatic brain damage; dementia; positive GBA mutation test; positive viral marker; high-risk for surgery; uncontrolled mental illnesses; pallidotomy, thalamotomy, or DBS; Contraindications for MRI; intolerance to cotrimoxazole, immunosuppressive regimen, MRI contrast material or bovine serum derivatives; cell transplantation; pregnancy or lactation; history of drug use or chronic alcohol use; history of taking immunosuppressives, antipsychotics, anticonvulsants, anticoagulants, apomorphine, phenol or other drugs related to the treatment of dystonia or muscle cramps in the last three months; consumption of botulism poison in the last six months; Patients who, according to the researcher's opinion, are not suitable for conducting the study safely;

Intervention groups
All patients will undergo the injection of cell suspension in the striatum of both hemispheres.

Main outcome variables
Feasibility, safety (as the main objective of the study: Occurrence of adverse events

General information

Reason for update

Acronym
DOPASON study

IRCT registration information
IRCT registration number: **IRCT20160704028786N2**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

Registration date
2023-08-12, 1402/05/21

Registrant information

Name
Hossein Baharvand

Name of organization / entity
Royan Institute

Country
Iran (Islamic Republic of)

Phone
+98 21 2230 6485

Email address
baharvand@royaninstitute.org

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01
Expected recruitment end date
2024-06-21, 1403/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
DOPASON project: The Assessment of Safety and Feasibility of Intra-Striatal Transplantation of Human Embryonic stem cell-derived Dopaminergic Progenitors (DopaCell) in Parkinson’s disease: A Multicenter Phase I Clinical Trial

Public title
Safety and Feasibility of DopaCell transplantation in patients with Parkinson's disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of PD based on MDS Clinical Diagnostic Criteria for Parkinson's Disease (2015) The duration of the disease must be at least 5 years from the time of diagnosis Patients should have ON- and OFF-period and have Hoehn Yahr stage≥III during OFF-period and Hoehn Yahr stage<III during ON-period. Patients should only receive drug treatment at the time of study entry The patient does not have levodopa-induced dyskinesia The patient must have at least 30% response to levodopa therapeutic dose (based on UPDRS part III). The function of different organs based on laboratory evaluations, within 7 days of entering the study, should include: (1) neutrophil count ≥2000/µl (2) platelet count ≥100,000/µl (3) AST/ALT ≤3 times the maximum normal value at the intervention site (4) total bilirubin value ≤ 1.5 times the maximum normal value at the intervention site (5) eGFR level: greater than or equal to 60 ml/min/1.73 square meters. Before entering the study, the patient must submit a written consent form to participate in the research. (If the patient is unable to write due to illness, the patient's legal guardian must complete the written consent form, or if the legal guardian is not present, the patient must verbally inform the researcher of consent to enter the study.)
Exclusion criteria:
Patient with underlying disease (Such as abnormal immune system) Patient with symptomatic brain damage confirmed by MRI Patient with dementia. Patient with a GBA mutation. Patient with an abnormal coagulation system Patient with positive viral markers. Patient considered high-risk for surgical intervention (high risk of cardiovascular disease, pulmonary and other systemic diseases in pre-op evaluation) Patient with concurrent neurological disorder such as malignancy, neoplasm, epilepsy, cerebral hemorrhage or a positive history of it, or uncontrolled mental diseases. Patient with contraindications for MRI (the presence of metal in the body, the presence of a pacemaker in the body, claustrophobia, with artificial heart valves that are incompatible with MRI, body weight not within the tolerable range for the MRI table). Patient cannot tolerate the use of immunosuppressive regimens (including azathioprine, prednisolone, tacrolimus), concomitant medications (such as levodopa, carbidopa, MRI contrast agent), cotrimoxazole, or bovine serum derivatives. Patient that has undergone another cell transplantation. Patient that is pregnant or lactating. Patient who, according to the researcher's opinion, is not suitable for conducting the study safely. Patient with a history of chronic alcohol or drug use. Patient with a history of taking immunosuppressive drugs, antipsychotic drugs, anticonvulsant drugs, anticoagulant drugs, or apomorphine in the last three months. Patient with a history of using botulism toxin, phenol, or any drug related to the treatment of dystonia or muscle cramps in the six months leading to the study.
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **4**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Royan Institute-Academic Center for Education, Culture, and Research
Street address
No. 12, Hafez St., Banihashem St., Qasem Soleimani Expressway (Resalat Ave).
City
Tehran
Province
Tehran
Postal code
1665659911

Approval date
2023-08-08, 1402/05/17
Ethics committee reference number
IR.ACECR.ROYAN.REC.1402.040

Health conditions studied

1

Description of health condition studied
Parkinson's disease
ICD-10 code
G20
ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Safety and feasibility
Timepoint
during hospitalization, month 1, 3, 6, 9, 12 after intervention
Method of measurement
Checklist of adverse events based on CTCAE version 4

Secondary outcomes

1

Description
Clinical presentation in On-period
Timepoint
During hospitalization, 1, 3, 6, 9, 12 months after the intervention
Method of measurement
MDS-UPDRS questionnaire

2

Description
Clinical presentation in Off-period
Timepoint
Month 1, 6, 12 after the intervention
Method of measurement
MDS-UPDRS questionnaire

3

Description
Parkinson's disease severity
Timepoint
Months 1, 3, 6, 9, 12 after the intervention
Method of measurement
Hoehn-Yahr scale

4

Description
Quality of life
Timepoint
Months 1, 3, 6, 9, 12 after the intervention
Method of measurement
PDQ-39 questionnaire

5

Description
medication dosage
Timepoint
Months 1, 3, 6, 9, 12 after the intervention
Method of measurement
Levodopa equivalent dose

6

Description
On- and Off-period with and without dyskinesia
Timepoint
Months 1, 6, 12 after intervention
Method of measurement
Hauser diary checklist

7

Description
Graft function
Timepoint
Month 12 after intervention
Method of measurement
TRO-DaT SPECT imaging

8

Description
Psychiatric status
Timepoint
During hospitalization, 1, 3, 6, 9, 12 months after intervention
Method of measurement
Psychiatric interview, Montreal cognitive assessment questionnaires, Beck anxiety inventory, Beck depression inventory, Positive and negative syndrome scale, Brief psychiatric rating scale, Yale-brown obsessive compulsive scale, Hamilton depression rating scale.

Intervention groups

1

Description
The cell suspension prepared for transplantation includes caudal ventral mesencephalic dopaminergic progenitor cells derived from human embryonic stem cells (DopaCell) with a concentration of 100,000 cells per microliter, which will be prepared under GMP conditions and with clinical quality. The cell suspension will be injected into the striatum of both hemispheres of the patient during one stereotactic surgery. In each hemisphere, three routes inside the striatum (in the putamen and in front, at, and behind the anterior commissure) will be chosen for the injection of cell suspension, and the total volume of injection for each

hemisphere will be 50 microliters. The cell suspension will be injected at a rate of one microliter per minute. To perform this surgery, the usual instrument used to move the microelectrodes in DBS will be used. The injection routes will be determined for each patient using imaging and routing software used in DBS surgery.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool akram hospital
Full name of responsible person
Mohammad Roohani, Mansoor Parvaresh Rizi
Street address
Hazrat Rasool akram hospital, Mansoori ave, Sattarkhan street
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 8860 2217
Email
Rasoolhospital@iums.ac.ir

2

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Vahid Reza Ostovan, Ahmad Soltani
Street address
Namazi hospital, Namazi Sq., Zand St.
City
Shiraz
Province
Fars
Postal code
1331171936
Phone
+98 71 3647 4332
Email
nemazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Hossein Baharavand
Street address
Royan Institute for Stem Cell Biology and Technology, Hafez Alley Nr.2 , Banihashem, Shahid Soleymani highway
City
Tehran
Province
Tehran
Postal code
1665659911
Phone
+98 21 2356 2000
Email
info@royaninstitute.org
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Science and Technology Vice-Presidency
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

2

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Roohani; Mansour Parvaresh Rizi
Street address
ran University of Medical Sciences (IUMS), Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
14496-14535
Phone
+98 21 8670 2030
Email
intl@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Science and Technology Vice-Presidency
Proportion provided by this source
100
Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

3

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vahid Reza Ostovan; Ahmad Soltani

Street address

Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3212 2884

Email

gsia@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Science and Technology Vice-Presidency

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Sarvenaz Salahi

Position

Medical doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Royan Institute for Stem Cell Biology and Technology, Hafez Alley Nr.2 , Banihashem, Shahid Soleymani highway

City

Tehran

Province

Tehran

Postal code

16635148

Phone

+98 21 2356 2000

Email

salahi13639@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences; Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Roohani; Vahid Reza Ostovan

Position

Associate Professor; Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Movement disorders

Street address

Royan Institute for Stem Cell Biology and Technology, Hafez Alley Nr.2 , Banihashem, Shahid Soleymani highway

City

Tehran

Province

Tehran

Postal code

16635148

Phone

+98 21 2356 2000

Email

salahi13639@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Sarvenaz Salahi

Position

Medical doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Royan Institute for Stem Cell Biology and Technology, Hafez Alley Nr.2 , Banihashem, Shahid Soleymani highway

City
Tehran
Province
Tehran
Postal code
16635148
Phone
+98 21 2356 2000
Email
salahi13639@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available