

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Visual-spatial attention and risk decision making of Parkinson's disease Patients in Comparison with healthy individuals and the effect of deep brain stimulation on it

Protocol summary

Study aim

The effect of deep brain stimulation surgery on cognitive disorders in patients with Parkinson's

Design

This study includes a study on three groups of participants who are selected non-randomly and in a controlled manner: 1 Experimental group: Patients with Parkinson's candidate for deep brain stimulation surgery, 2 Control group : Patients with Parkinson's without the need for deep brain stimulation surgery, 3 Second control group: healthy people without Parkinson's disease and neurodegenerative diseases, All three groups are selectively and non-randomly placed in the desired groups. We will have a sample size of 12 people in each group and a total of 36 cases. Clinical trial has two control groups, with parallel, non-random groups.

Settings and conduct

Imam Reza Clinic of Shiraz , Namazi Hospital of Shiraz and Kosar Hospital of Shiraz How to implement and select study cases will be done at the discretion and opinion of the consultant (neurologist).

Participants/Inclusion and exclusion criteria

All patients with Parkinson's are diagnosed by a neurologist, Have a minimum literacy, Satisfaction with participation in research, No neurodegenerative disease other than Parkinson's disease, Minimum age 15 years

Intervention groups

We include Parkinson's patients who, according to a neurologist, are candidates for deep brain stimulation surgery, in the experimental group, and Parkinson's patients, who do not need to undergo deep brain stimulation surgery at least until the end of the study.

Main outcome variables

Cognitive function, especially spatial visual attention and their level of risk

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220227054136N1**

Registration date: **2022-03-21, 1401/01/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-21, 1401/01/01**

Update count: **0**

Registration date

2022-03-21, 1401/01/01

Registrant information

Name

Mahshad Sohrabi jahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5444 9616

Email address

m.sohrabi1374@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-11, 1400/12/20

Expected recruitment end date

2022-11-11, 1401/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Visual-spatial attention and risk decision making of Parkinson's disease Patients in Comparison with healthy individuals and the effect of deep brain stimulation on it

Public title

The effect of deep brain stimulation on cognitive disorders in Parkinson's disease patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

all Parkinson's disease patients Persons with a minimum age of 15 years Minimum literacy

Exclusion criteria:

People with neurodegenerative diseases except for Parkinson's patients Inability to perform tests for any reason Dissatisfaction with participation in research

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

4 Tavakoli, N Edalat street

City

Shiraz

Province

Fars

Postal code

7168637502

Approval date

2022-02-01, 1400/11/12

Ethics committee reference number

IR.SUMS.REC.1400.846

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

Spatial visual attention scores in the Simon task

Timepoint

First pre-test about 20 to 10 days before surgery, second pre-test about 3 to 1 day before surgery, first post-test 1 to 7 days after surgery, second post-test about 40 days after surgery, third post-test about 3 Month after surgery

Method of measurement

simon task

2

Description

Risk ratings in the Cambridge Risk Task have been modified

Timepoint

First pre-test about 20 to 10 days before surgery, second pre-test about 3 to 1 day before surgery, first post-test 1 to 7 days after surgery, second post-test about 40 days after surgery, third post-test about 3 Month after surgery

Method of measurement

Modified Cambridge Risk Task

Secondary outcomes

empty

Intervention groups

1

Description

Control group 1 : This group includes Parkinson's patients without the need for deep brain stimulation surgery and no therapeutic interventions are performed on them.

Category

Behavior

2

Description

Control group 2 : This group includes healthy people without Parkinson's disease and no therapeutic intervention is performed on them.

Category
Behavior

3

Description

Intervention group: Parkinson's patients are candidates for deep brain stimulation surgery performed by a surgical intervention surgeon.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Mahshad Sohrabi Jahromi

Street address

Imam Reza Clinic , Zand Boulevard , shiraz, fars

City

Shiraz

Province

Fars

Postal code

7134814734

Phone

+98 71 3612 1000

Fax

+98 71 3647 4673

Email

motahari@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kordestan university

Full name of responsible person

Dr. Ahmad Sohrabi

Street address

Kordestan university, Pasdaran boulevard, Sanandaj , Iran

City

Sanandaj

Province

Kurdistan

Postal code

6617715175

Phone

+98 87 3366 4600

Email

info@uok.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

cognitive sciences and technologies council

Proportion provided by this source

40

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

The University of Kordestan

Full name of responsible person

Mahshad Sohrabi Jahromi

Position

University student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Tavakoli4 , N Edalat Blvd , Shiraz

City

Shiraz

Province

Fars

Postal code

7168637502

Phone

+98 71 5444 9616

Email

m.sohrabi1374@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Kordestan

Full name of responsible person

Dr. Ahmad Sohrabi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

The University of Kordestan , Pasdaran Blvd , Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code
6617715175
Phone
+98 87 3366 4600
Email
sohrabya@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
The University of Kordestan
Full name of responsible person
Mahshad Sohrabi Jahromi
Position
University Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Tavakoli 4 , N Edalat Blvd , Shiraz
City
Shiraz
Province
Fars
Postal code
7168637502
Phone
+98 71 5444 9616
Email
m.sohrabi1374@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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Not all information about the participants in the study will be available and only part of it related to the results will be available.

When the data will become available and for how long
The data access period will start approximately one year after the results are published.

To whom data/document is available
All researchers whose field of study is the prevention, diagnosis and treatment of neurodegenerative patients will have access to information.

Under which criteria data/document could be used
They are allowed to apply if non-governmental or private centers decide to take measures for the well-being and rehabilitation of patients or their caregivers and need part of the results.

From where data/document is obtainable
Mahshad Sohrabi Jahromi m.sohrabi1374@gmail.com Dr. Ahmad Sohrabi sohrabya@gmail.com

What processes are involved for a request to access data/document
Provide credible evidence that the researcher is in the field of neurodegenerative patients or provide credible evidence that a particular organization or industry will take action for the well-being of these patients or their caregivers.

Comments