Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of sevoflurane versus propofol on the quality of neurologic recording, recovery time and hemodynamic profile in deep brain stimulation for Parkinson surgery

Protocol summary

Study aim
To compare the effects of Propofol and Sevoflurane on the quality of the neurological examination, hemodynamic profile and duration of recovery from anesthetics in DBS surgery for Parkinson's disease
Design
Randomized double-blind clinical trial
Settings and conduct
Patients were randomly allocated into two groups of propofol and sevoflurane. The patients, assessor and the analyzer were blinded to the assignments. The setting was Rasoul Akram University hospital
Participants/Inclusion and exclusion criteria
Patients with severe Parkinson undergoing DBS Surgery
Intervention groups
Propofol Sevoflurane
Main outcome variables
Time to wake up the patient after discontinuing anesthetics Firing Rate Peak To Peak

General information

Reason for update
Acronym
Deep Brain Stimulation-DBS
IRCT registration information
IRCT registration number: **IRCT20101026005026N8**
Registration date: **2018-05-07, 1397/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-07, 1397/02/17**
Update count: **0**
Registration date
2018-05-07, 1397/02/17

Registrant information
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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research - Iran University of Medical Sciences

Expected recruitment start date
2017-05-01, 1396/02/11
Expected recruitment end date
2018-05-20, 1397/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of sevoflurane versus propofol on the quality of neurologic recording, recovery time and hemodynamic profile in deep brain stimulation for Parkinson surgery

Public title
The effect of anesthetics in DBS surgery in Parkinson patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Patients with Advanced Parkinson's Patients with severe dyskinesia due to levodopa administration

Exclusion criteria:

Severe cardiovascular or ischemic diseases Uncontrolled hypertension CVA Cancer or any life-threatening agent Taking anti-coagulants Severe psychiatric disorders

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly allocated to the propofol/sevoflurane groups. Simple Randomization was performed using a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients, outcome assessor and data analyser were blinded to the assignments

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Approval date

2017-04-12, 1396/01/23

Ethics committee reference number

IR.IUMS.RES.1395.9211174005

Health conditions studied

1

Description of health condition studied

Parkinson disease

ICD-10 code

G20

ICD-10 code description

Hemiparkinsonism Paralysis agitans Parkinsonism or Parkinson disease: NOS idiopathic primary

Primary outcomes

1

Description

Duration of recovery from anesthetics

Timepoint

During the targeting of subthalamic nucleus

Method of measurement

Minutes using a chronometer

2

Description

Blood pressure

Timepoint

Every 5 minutes during the maintenance of anesthesia

Method of measurement

Automatic noninvasive sphyngometer

Secondary outcomes

1

Description

Heart rate

Timepoint

Before induction, half an hour after induction, before discontinuation of anesthetics, during neurological examination every 15 minutes, at the end of surgery

Method of measurement

Continuous ECG monitoring

Intervention groups

1

Description

Propofol 30 microgram/kg for maintenace of anesthesia

Category

Treatment - Drugs

2

Description

Sevoflourane 1% for maintenance of anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
Masood Mohseni
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Iran University of Medical Sciences

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
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Masood mohseni
Position
Associate professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data regarding primary and secondary outcomes will be available
When the data will become available and for how long
immediately after publication
To whom data/document is available
only faculty members and academic institutions
Under which criteria data/document could be used
The result of further analysis may not be presented to public without permission
From where data/document is obtainable
masood.mohseni@gmail.com
What processes are involved for a request to access data/document
A reasonable request from an academic source will be responded within 10 working days
Comments