

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of the effect of oral propranolol on hemodynamics and sedation of patients in stereotaxic surgery

Protocol summary

Study aim

Evaluation of the effect of oral propranolol on hemodynamics and sedation of patients in stereotaxic surgery

Design

Clinical trial with control group with parallel groups, phase 2-3 on 72 patients

Settings and conduct

This study is performed in Al-Zahra Hospital in Isfahan. Patients will be treated in two ways and the hemodynamics and sedation of patients will be recorded and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 20 and 65 years, informed consent to enter the study, candidate for stereotaxic surgery, lack of drug sensitivity
Exclusion criteria: changing the surgical plan for any reason, changing the anesthesia plan for any reason

Intervention groups

Intervention group: Patients in this group receive propranolol in a dose of 20 mg, 2 hours before the operation. Blood pressure and sedation of patients in this group will be measured in one, three, five, ten, fifteen minutes after the intervention and at the time of entering the recovery and every fifteen minutes in the recovery. Control group: Patients in this group receive placebo tablets, which are very similar to propranolol, 2 hours before the operation. Blood pressure and sedation of patients in this group will be measured in one, three, five, ten, fifteen minutes after the intervention and at the time of entering the recovery and every fifteen minutes in the recovery.

Main outcome variables

Blood pressure and sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051574N1**

Registration date: **2021-07-07, 1400/04/16**

Registration timing: **prospective**

Last update: **2021-07-07, 1400/04/16**

Update count: **0**

Registration date

2021-07-07, 1400/04/16

Registrant information

Name

Ghasem Mohammadsharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3729 4005

Email address

mohammadsharifi.ghasem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-10, 1400/05/19

Expected recruitment end date

2021-09-10, 1400/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral propranolol on hemodynamics and sedation of patients in stereotaxic surgery

Public title

Propranolol and hemodynamics and sedation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 to 65 years
Informed consent to enter the study
Candidate for stereotaxic surgery
Lack of drug sensitivity

Exclusion criteria:

Changing the surgical plan for any reason
Changing the anesthesia plan for any reason

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-10-16, 1399/07/25

Ethics committee reference number

IR.MUI.MED.REC.1399.636

Health conditions studied

1

Description of health condition studied

Brain Tumor

ICD-10 code

C71.7

ICD-10 code description

Malignant neoplasm of brain stem

Primary outcomes

1

Description

Blood pressure

Timepoint

In minute one, three, five, ten, fifteen after the intervention and at the time of entering the recovery and every fifteen minutes in the recovery

Method of measurement

Measured by barometer

2

Description

Sedation

Timepoint

In minute one, three, five, ten, fifteen after the intervention and at the time of entering the recovery and every fifteen minutes in the recovery

Method of measurement

Richmond criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group receive propranolol in a dose of 20 mg, 2 hours before the operation. They will also be anesthetized with fentanyl and midazolam.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group receive placebo tablets, which are very similar to propranolol, 2 hours before the operation. They will also be anesthetized with fentanyl and midazolam.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Mehrdad Masoudifar

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0042

Email

parsa.alinezhad85@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

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Postal code

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Phone

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haghjoo.sh@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mehrdad Masoudifar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Contact

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Person responsible for updating data

Contact

Name of organization / entity

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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

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Website of the Research Committee of Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments