Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparative study of the effect of clonidine with placebo before surgery on hemodynamics and sedation of patients in stereotaxic surgery

Protocol summary

Study aim
Comparative study of the effect of clonidine with placebo before surgery 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, conscious 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 clonidine in a dose of 0.2 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 clonidine, 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: **IRCT20210614051574N2**
Registration date: **2021-07-12, 1400/04/21**
Registration timing: **prospective**

Last update: **2021-07-12, 1400/04/21**
Update count: **0**

Registration date
2021-07-12, 1400/04/21

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
Comparative study of the effect of clonidine with placebo before surgery on hemodynamics and sedation of patients in stereotaxic surgery

Public title
Clonidine and hemodynamics and sedation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 to 65 years Conscious 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)
Not randomized
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
Isfehan
Postal code
8174673461
Approval date
2020-12-10, 1399/09/20
Ethics committee reference number
IR.MUI.MED.REC.1399.809

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 clonidine in a dose of 0.2 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.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group receive placebo tablets, which are very similar to clonidine, 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.

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

Isfehan

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

City

Isfahan

Province

Isfehan

Postal code

8174673118

Phone

+98 31 3668 0048

Email

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

Street address

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

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0042

Email

parsa.alinezhad85@gmail.com

Person responsible for scientific 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

Street address

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

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0042

Email

parsa.alinezhad85@gmail.com

Person responsible for updating data

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
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0042
Email
parsa.alinezhad85@gmail.com

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