

# 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

Isfahan

##### 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**

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

**City**

Isfahan

**Province**

Isfahan

**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

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

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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**