

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A Comparison of Dexmedetomidine and Magnesium Sulfate as an Anesthetic Adjuant in trans-Sphenoid pituitary surgery

#### Protocol summary

##### Study aim

A Comparison of Dexmedetomidine and Magnesium Sulfate as an Anesthetic Adjuant in trans-Sphenoid pituitary surgery

##### Design

In this randomized clinical trial study, 60 patients will be randomly divided into two groups, D and S, using quadruple blocks. After anesthesia of the patients, each patient will receive his intervention protocol and the two groups will be compared in terms of hemodynamic status and pain intensity after injecting the relevant drugs.

##### Settings and conduct

Patients participating in this study will be evaluated and intervened in the operating room of Loghman Hospital, and after being divided into intervention groups, will receive the relevant drug after anesthesia. During anesthesia, patients' hemodynamic status and pain intensity will be compared.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for pituitary surgery by transsphenoid method, general anesthesia and consent to participate in the study and Exclusion criteria: Sensitivity to the studied drugs and taking drugs that increase intracranial pressure.

##### Intervention groups

The participants will be divided into intervention 1 and intervention 2 groups. In intervention group 1, they will receive dexmedetomidine in the form of one microgram/kg bolus within ten minutes, and they will receive this medicine in the form of half a microgram/kg per hour until the end of the surgery. In intervention group 2: they will receive magnesium sulfate medicine in the form of 50 mg/kg bolus within ten minutes and they will receive this medicine in the form of 15 micrograms/kg per hour until the end of the surgery. Hemodynamic status will be recorded during surgery and pain intensity will be monitored for 12 hours after surgery.

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220528055003N1**

Registration date: **2022-07-13, 1401/04/22**

Registration timing: **prospective**

Last update: **2022-07-13, 1401/04/22**

Update count: **0**

##### Registration date

2022-07-13, 1401/04/22

##### Registrant information

##### Name

Nina Pilevar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5102 5000

##### Email address

ninapilevar@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-21, 1401/04/30

##### Expected recruitment end date

2022-09-21, 1401/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

A Comparison of Dexmedetomidine and Magnesium Sulfate as an Anesthetic Adjuvant in trans-Sphenoid pituitary surgery

### Public title

Effects of dexmedetomidine and magnesium sulfate in the administration of pituitary surgery anesthesia

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Candidate for pituitary surgery by trans-sphenoid method Candidate for general anesthesia Satisfaction to participate in the study

#### Exclusion criteria:

Sensitivity to the studied drugs Taking drugs that increase intracranial pressure

### Age

From **18 years** old to **75 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Outcome assessor

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

This is a simple randomized clinical trial in which people are randomly assigned to study groups; In such a way that the required number of drugs are placed in opaque sealed envelopes that are coded. Each of the codes is also written on a paper, folded and placed inside a box, after entering the operating room, each patient takes out one of the papers from the box, the envelope has the same number as the number inside the selected paper, intervention It is applied to the patient. This work continues until the end of the papers, so that the number of patients reaches the desired volume in the groups.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

The outcome researcher will be unaware of the grouping of participants and the type of drug injected into patients; Therefore, the rejection of the study flow will remain blind.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

##### Street address

Loghman hakim Hospital. Makhsoos Ane, Southern Karehar Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

3556896623

#### Approval date

2020-06-28, 1399/04/08

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1399.274

## Health conditions studied

### 1

#### Description of health condition studied

Pain

#### ICD-10 code

G89.11

#### ICD-10 code description

Acute pain due to trauma

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Up to 12 hours after the intervention and once every hour

#### Method of measurement

Visual Analog Scale

## Secondary outcomes

### 1

#### Description

Hemodynamic status

#### Timepoint

From the beginning of the intervention to the end of the intervention (every three minutes)

#### Method of measurement

Monitoring hemodynamic status with the help of cardiopulmonary monitoring

## Intervention groups

## 1

### Description

Intervention group: Thirty patients who are candidates for pituitary surgery transferred to the operating room of Loghman Hakim Hospital (Tehran) will be included in this group randomly. After injection of anesthesia drugs and intratracheal intubation, they will receive dexmedetomidine in the form of one microgram / kg in ten minutes as a bolus, and until the end of the surgery, they will receive this drug in the form of half a microgram / kg per hour. Hemodynamic status will be recorded during surgery and pain intensity will be monitored for up to 12 hours after surgery.

### Category

Treatment - Drugs

## 2

### Description

Intervention group: Thirty patients who are candidates for pituitary surgery transferred to the operating room of Loghman Hakim Hospital (Tehran) will be included in this group randomly. After injecting anesthesia and intubation intubation, they will receive 50 mg / kg magnesium sulfate as a bolus within ten minutes and will receive 15 µg / kg per hour until surgery. Hemodynamic status will be recorded during surgery and pain intensity will be monitored for up to 12 hours after surgery.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Loghman Hakim Hospital

#### Full name of responsible person

Nina Pileh Var

#### Street address

Loghman Hakim Hospital, Special Street, South Kargar Street,

#### City

Tehran

#### Province

Tehran

#### Postal code

3696585859

#### Phone

+98 914 411 3557

#### Email

Ninapilevar@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Masoud Nashibi

#### Street address

Loghman Hakim Hospital, Special Street, South Kargar Street

#### City

Tehran

#### Province

Tehran

#### Postal code

3696585859

#### Phone

+98 914 411 3557

#### Email

Masoudnashibi@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Nina Pilevar

#### Position

Fellowship assistant

#### Latest degree

Specialist

#### Other areas of specialty/work

Anesthesiology

#### Street address

Loghman Hakim Hospital, Special Street, South Kargar Street

#### City

Tehran

#### Province

Tehran

#### Postal code

3696585859

#### Phone

+98 21 5102 5000

#### Fax

#### Email

Ninapilevar@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nina Pilevar

**Position**

Fellowship assistant

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Loghman Hakim Hospital, Special Street, South Kargar Street

**City**

Tehran

**Province**

Tehran

**Postal code**

3696585859

**Phone**

+98 21 5102 5000

**Fax****Email**

Ninapilevar@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nina Pilevar

**Position**

Fellowship assistant

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Loghman Hakim Hospital, Special Street, South Kargar Street

**City**

Tehran

**Province**

Tehran

**Postal code**

3696585859

**Phone**

+98 21 5102 5000

**Fax****Email**

Ninapilevar@yahoo.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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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