Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Adjuant 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,

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3696585859

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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

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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

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Person responsible for updating data

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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