

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the effects of Dexmedetomidine and Metoprolol and Magnesium Sulphate in Reducing Blood Loss during Craniotomy

Protocol summary

Study aim

Comparing the effects of Dexmedetomidine and Metoprolol and Magnesium Sulphate in Reducing Blood Loss during Craniotomy

Design

A double-blind clinical trial study, 99 patients were randomly divided into 3 groups. The groups are in parallel. The trial phase is 3.

Settings and conduct

Candidates for general anesthesia in Valiasr hospital in Arak city are divided into 3 groups by simple randomization using block method. The study is double-blind. In this study, the supervisor knows about the grouping and prescribes the drugs for the patients, and the interns do not know about the prescribed drugs, and the follow-up of the patients is with the interns, and the analyst does not know about the grouping, and as a result The study will be double-blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 75 years; ASA class one and two; not suffering from coagulation disorders; no history of cardiovascular diseases; Body mass index less than 35; craniotomy candidate patients; having consent to enter the study; Absence of sensitivity to the study drugs

Intervention groups

Intervention group 1: 1 µg/kg of dexmedetomidine for 10 minutes as an initial dose, followed by 0.4 to 0.8 µg/kg per hour for maintenance dose. (Consumable dexmedetomidine is made by Elixir - Iran) Intervention group 2: The initial dose of 2.5 mg/kg and then 0.5 mg/kg per hour of metoprolol will be infused. (Alborz Daru Pharmaceutical Company - Made in Iran) Intervention group 3: The initial dose of magnesium sulfate 40 mg/kg of magnesium sulfate (magnesium sulfate 50%, one gram in 2 ml) will be infused in 30 minutes and then 10 mg/kg per hour will be infused. (Pharmaceutical company) Shahid Ghazi - Made in Iran)

Main outcome variables

Average hemoglobin, bleeding, surgeon satisfaction,

recovery time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N188**

Registration date: **2023-09-13, 1402/06/22**

Registration timing: **prospective**

Last update: **2023-09-13, 1402/06/22**

Update count: **0**

Registration date

2023-09-13, 1402/06/22

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Dexmedetomidine and Metoprolol and Magnesium Sulphate in Reducing Blood Loss during Craniotomy

Public title

Comparing the effects of Dexmedetomidine and Metoprolol and Magnesium Sulphate in Reducing Blood Loss during Craniotomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 75 years ASA class I and II Absence of coagulation disorders No history of cardiovascular diseases Proper control of blood pressure Absence of pregnancy No addiction to opioids Body mass index less than 35 Craniotomy candidate patients Having consent to enter the study Absence of sensitivity to the study drugs The presence of creatinine less than 1/5 Absence of platelet count less than 150 thousand Serum magnesium is less than or equal to 2.5

Exclusion criteria:

Dissatisfaction

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 3 groups(intervention) using a permuted balanced block randomization method with the size of blocks 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the supervisor knows about the grouping and prescribes the drugs for the patients, and the interns do not know about the prescribed drugs, and the follow-up of the patients is with the interns, and the analyst does not know about the grouping, and as a result, the study will be double-blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee Arak University Of Medical Sciences

Street address

Dr Mohammad Rafiei, Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

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Province

Markazi

Postal code

38149578558

Approval date

2023-07-04, 1402/04/13

Ethics committee reference number

IR.ARAKMU.REC.1402.105

Health conditions studied**1****Description of health condition studied**

Craniotomy surgery

ICD-10 code

Q00.1

ICD-10 code description

Craniorachischisis

Primary outcomes**1****Description**

Average hemoglobin

Timepoint

Before and 12 hours after surgery

Method of measurement

Blood test

2**Description**

Bleeding

Timepoint

during surgery

Method of measurement

Based on scoring 1 to 4 bleeding volume

3**Description**

Consent of the surgeon

Timepoint

After surgery

Method of measurement

Score 3 points(zero means bad, one means average and two means good)

4**Description**

Recovery time

Timepoint

End of study

Method of measurement

chronometer

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: 1 µg/kg of dexmedetomidine for 10 minutes as an initial dose, followed by 0.4 to 0.8 µg/kg per hour for maintenance dose. (Consumable dexmedetomidine is made by Elixir - Iran)

Category

Treatment - Drugs

2**Description**

Intervention group 2: The initial dose of 2.5 mg/kg and then 0.5 mg/kg per hour of metoprolol will be infused. (Alborz Daru Pharmaceutical Company - Made in Iran)

Category

Treatment - Drugs

3**Description**

Intervention group 3: The initial dose of magnesium sulfate 40 mg/kg of magnesium sulfate (magnesium sulfate 50%, one gram in 2 ml) will be infused in 30 minutes and then 10 mg/kg per hour will be infused. (Pharmaceutical company) Shahid Ghazi - Made in Iran)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Behnam Mahmodie

Street address

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Person responsible for updating data

Contact

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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