Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

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

Protocol summary

Study aim
Comparing the effects of Dexmedetomidine and Metoprolol and Magnesium Sulphate in ReducingBlood 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

Country
Iran (Islamic Republic of)

Phone
+98 86 3222 2003

Email address
f.farokhi@arakmu.ac.ir

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 ReducingBlood Loss during Craniotomy

Public title
Comparing the effects of Dexmedetomidine and Metoprolol and Magnesium Sulphate in ReducingBlood Loss during Craniotomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 75 years ASA class Iand 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 squre, Sardasht, Arak

City
Arak

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 squre, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

mahmodie@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Davoud Hekmatpou

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

hekmatpou@gmail.com

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
Anesthesiology
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
modir.he@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Behnam Mahmodie
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
mahmodie@arakmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad Amin Khademi
Position
medicine student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
khademi@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