

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Dexmedetomidine and Metoprolol on reducing intraoperative bleeding in patients with craniotomy candidate due to head trauma

Protocol summary

Study aim

Comparison of the effect of Dexmedetomidine and Metoprolol on reducing intraoperative bleeding in patients with craniotomy candidate due to head trauma

Design

This is a double-blind clinical trial conducted on 66 patients with severe head trauma who have undergone craniotomy and who have been referred to the Valiasr Hospital in Arak. Patients are divided in three groups by random numbers.

Settings and conduct

This is a double-blind clinical trial in Valiasr Hospital in Arak. Patients are divided in three groups by random numbers. We check bleeding and mortality.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with head trauma; patients with ASA class I and II; consciously informed form; candidates of craniotomy due to severe head trauma; maximum operation duration of 150 minute; Patients are operated by a neurosurgeon; 15-75 years Exclusion criteria: hypersensitivity to dexmedetomidine and metoprolol; their operation will take more than 150 minutes; patients with severe head trauma candidates of craniotomy that their legal guardian refuse the informed written consent for participation in the study; Patients with a past medical history of cardio-vascular diseases, uncontrolled diabetes, seizure and epilepsy, renal failure, liver failure, coagulation disorders, previous cerebrovascular accident or recent myocardial infarction

Intervention groups

Intervention group 1: We inject 1 micro gram in kilogram Dexmedetomidine in loading dose and 0.5 micro gram in kilogram Dexmedetomidine in hours in Infusion.
Intervention group 2: We inject 2/5 milligram in kilogram Metoprolol in loading dose and 0.5 micro gram in kilogram Metoprolol in hours in Infusion. control group: We inject 5 milliliter distilled water as loading dose and

120 milliliter distilled water in Infusion.

Main outcome variables

bleeding and mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190417043302N1**

Registration date: **2019-05-12, 1398/02/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-12, 1398/02/22**

Update count: **0**

Registration date

2019-05-12, 1398/02/22

Registrant information

Name

Rezvan Rahimifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3403 0520

Email address

sh.zargar@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-13, 1397/02/23

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Dexmedetomidine and Metoprolol on reducing intraoperative bleeding in patients with craniotomy candidate due to head trauma

Public title

efficacy of Dexmedetomidine and metoral on reducing hemorrhage during craniotomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with head trauma Patients with ASA class I and II Patients that the informed written consent form has been filled out by their legal guardian in order to participate in the study Candidates of craniotomy due to severe head trauma Patients with severe head trauma candidates of craniotomy with a maximum operation duration of 150 min Patients with severe head trauma candidates of craniotomy that are operated by a neurosurgeon Patients with severe head trauma candidates of craniotomy aged between 15-75 years

Exclusion criteria:

Patients with severe head trauma candidates of craniotomy which have hypersensitivity to dexmedetomidine and metoprolol Patients with severe head trauma candidates of craniotomy that their legal guardian refuse the informed written consent for participation in the study. Patients with a past medical history of cardio-vascular diseases, uncontrolled diabetes, seizure and epilepsy, renal failure, liver failure, coagulation disorders, previous cerebrovascular accident or recent myocardial infarction

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random number table in division of groups in two groups A and B . Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we set the framework for our statistical society. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that,

the numbers control the path. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers were used for intervention group and odd numbers were used for the control group. Allocation concealment: Numbered drug containers

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants will not be informed about the drug administered; however, informed written consent will be obtained from the legal guardian before enrollment in the study. Drugs will be prepared by the anesthesiologist in 5 ml and 20 ml syringes for both groups and labelled A and B. The anonymous syringes will then be given to an anesthesiology resident for administration. Moreover, the intern responsible for the project will also fill out the questionnaires and document data as groups A and B. Therefore, both the anesthesiology resident and intern will be blinded to group assignment and drug administration.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.ARAKMU.REC.1397.006

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

Craniotomy

ICD-10 code

S08.89

ICD-10 code description

Traumatic amputation of other parts of head

Primary outcomes

1

Description

Bleeding

Timepoint

Every 15 minutes to end of surgery

Method of measurement

Observation

2

Description

mortality

Timepoint

After surgery

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1:We inject 1 micro gram in kilogram Dexmedetomidine in loading dose and 0.5 micro gram in kilogram Dexmedetomidine in hours in Infusion.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group 2:We inject 2/5 milligram in kilogram Metoprolol in loading dose and 0.5 micro gram in kilogram Metoprolol in hours in Infusion.

Category

Treatment - Drugs

3

Description

Control group: We inject 5 milliliter distilled water as loading dose and 120 milliliter distilled water in Infusion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Alireza Kamali

Street address

Valiasr hospital, Valiasr squire

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

alikalaliir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

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

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

m.arjmandzadegan@arakmu.ac.ir

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 Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr hospital, Valiasr square

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

alikalaliir@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr hospital, Valiasr square

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

alikalaliir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Rezvan Rahimifar

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Hepco Ane

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3403 0520

Fax

Email

sh.zargar@arakmu.ac.ir

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