Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 operatiion will take more than 150 minutes; patients with severe head trauma candidates of craniotomy that their legal gurdian refuse the informed written consent for participation in the study; Patients with a past medical history of cardio-vascvular 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

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Iran (Islamic Republic of)

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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 fillede out by their legal gurdian 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 hypersensitivy to dexmedetomidine and metoprolol Patients with severe head trauma candidates of craniotomy that their legal gurdian refuse the informed written consent for participation in the study. Patients with a past medical history of cardio-vascvular 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 gurdian before enrollment in the study. Drugs will be prepared by the anesthisiologist 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 comittee, Research center, Payambar Azam complex, Basij squre ,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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
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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 Alireza Kamali
Position
Associate professor
Latest degree
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Other areas of specialty/work
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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