Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of the effect of Labetalol and Remifentanil and Dexmedetomidine in control of bleeding during Craniotomy

Protocol summary

Study aim
Comparison of the effect of Labetalol and Remifentanil and Dexmedetomidine in control of bleeding during Craniotomy

Design
The study will be double blind and clinical trial.90 patients will be randomly divide into 3 groups. The groups are parallel. The trial phase is 3.

Settings and conduct
Patients with Craniotomy in Valiasr hospital in Arak are divided into 3 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 75 years, ASA Class One and Two,no coagulation disorders, no history of cardiovascular disease, not addicted to opioids, body mass index more than 35, candidate patients for craniotomy Exclusion criteria: dissatisfaction with surgery, platelet count less than 150 thousand

Intervention groups
Intervention group 1: A bolus dose of 10 millilitre of normal saline is administered for 10 minutes and then remifentanil is infused at a dose of 0.1 micro gram per kilogram per minute until the end of surgery (GlaxoSmithKline Company (London - England).
Intervention group: 2: 1 micro gram in kilogram Dexmedetomidine will be infused for 10 minutes as the initial dose followed by 0.4 to 0.8 micro gram in kilogram in hours to maintain the infusion dose.
(Dexmedetomidine used by Elixir Company - Iran)
Intervention group 3: 0.25 milligram in kilogram Labetalol intravenously as the initial dose is slow and infused within 10 minutes, followed by 1-2 milligram in kilogram intravenously to maintain the infusion dose.
(Kern Pharma SL - Spain)

Main outcome variables
Surgeon satisfaction, bleeding, mean hemoglobin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N167**
Registration date: **2021-10-14, 1400/07/22**
Registration timing: **prospective**

Last update: **2021-10-31, 1400/08/09**
Update count: **1**

Registration date
2021-10-14, 1400/07/22

Registrant information

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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
2021-10-23, 1400/08/01

Expected recruitment end date
2022-10-23, 1401/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Labetalol and Remifentanil and Dexmedetomidine in control of bleeding during Craniotomy

Public title
Comparison of the effect of Labetalol and Remifentanil and Dexmedetomidine in control of bleeding during head surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 75 years ASA Class One and Two No coagulation disorders No history of cardiovascular disease Proper control of blood pressure Absence of pregnancy Not addicted to opioids Body mass index more than 35 Candidate patients for craniotomy

Exclusion criteria:
Dissatisfaction Existence of allergy to the studied drugs Platelet count less than 150 thousand Family history of thromboembolism

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: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into 3 groups using a permuted balanced block randomization method with the size of blocks 3 and 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 terms of patient blindness, the intern is responsible for completing information does not know the groupings, and general anesthesia and drug injections are performed by an anesthesiologist. Outcome assessor and data analyzer and participant are blind (double blind). Outcome assessor and data analyzer and participant don't aware from grouping. The intern is unaware of the drugs prescribed in each group and the anesthesiologist prepares the drugs and provides them to the intern. Also, the patients do not know about their group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics comittee 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
2021-06-13, 1400/03/23

Ethics committee reference number
IR.ARAKMU.REC.1400.052

Health conditions studied

1

Description of health condition studied
Craniotomy

ICD-10 code
I60

ICD-10 code description
Nontraumatic subarachnoid hemorrhage

Primary outcomes

1

Description
Surgeon satisfaction

Timepoint
After surgery

Method of measurement
Question from the surgeon

2

Description
Bleeding

Timepoint
During surgery

Method of measurement
observation

3

Description
Mean hemoglobin

Timepoint
Before and 12 hours after surgery
Method of measurement
Hemoglobin blood test(CBC diff)

Secondary outcomes

empty

Intervention groups

1

Description
ntervention group 1: A bolus dose of 10 millilitre of normal saline is administered for 10 minutes and then remifentanil is infused at a dose of 0.1 micro gram per kilogram per minute until the end of surgery (GlaxoSmithKline Company (London - England).
Category
Treatment - Drugs

2

Description
Intervention group: 2: 1 micro gram in kilogram Dexmedetomidine will be infused for 10 minutes as the initial dose followed by 0.4 to 0.8 micro gram in kilogram in hours to maintain the infusion dose. (Dexmedetomidine used by Elixir Company - Iran)
Category
Treatment - Drugs

3

Description
Intervention group 3: 0.25 milligram in kilogram Labetalol intravenously as the initial dose is slow and infused within 10 minutes, followed by 1-2 milligram in kilogram intravenously to maintain the infusion dose. (Kern Pharma SL - Spain)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Hesamodin Modir
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Sponsors / Funding sources

1

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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
Vice chancellor for research, 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 Esmaeel Moshiri
Position
Associate professor
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Specialist
Other areas of specialty/work
Anesthesiology

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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