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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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 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
    - 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**
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).

**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**
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Valiasr hospital
Full name of responsible person
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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**
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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