

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of dexmedetomidin, magnesium sulfate and osmolol for hypotension control in patients who are candidate for craniotomy surgery because of head injury

Protocol summary

Study aim

Aim of this study is comparison the effect of dexmedetomidin, magnesium sulfate and osmolol for hypotension control in patients who are candidate for craniotomy surgery because of head injury

Design

This study is clinical trial and double blind. 45 Patients with head injury who are candidates for craniotomy and referred to the Vali Asr Hospital in Arak.

Settings and conduct

This study is clinical trial and double blind. 45 Patients with head injury who are candidates for craniotomy and referred to the Vali asr Hospital in Arak. We divide patients in 3 groups randomly. This study is double blind. Outcome evaluator and analyzer are blind (double blind). Outcome evaluator and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Craniotomy candidate, both of gender
Exclusion criteria: Dissatisfaction

Intervention groups

We inject 1 milligram in kilogram Dexmedetomidin in Dexmedetomidin group, 1 milligram in kilogram osmolol in osmolol group, 50 milligram in kilogram in 100 milliliter normal saline as loading dose and we inject 0/5 milligram in kilogram in hours Dexmedetomidin infusion, 0/5 milligram in kilogram in hours osmolol infusion, 15 milligram in kilogram in hours magnesium sulfate infusion in each group.

Main outcome variables

heart rate, blood pressure, bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N86**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

Registration date

2018-10-07, 1397/07/15

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

2018-02-20, 1396/12/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of dexmedetomidin, magnesium sulfate and osmolol for hypotension control in patients

who are candidate for craniotomy surgery because of head injury

Public title
Comparison the effect of dexmedetomidin, magnesium sulfate and osmolol for hypotension control in patients who are candidate for craniotomy surgery because of head injury

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Craniotomy candidate both of gender
Exclusion criteria:
Dissatisfaction

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind.Outcome elevator and analyzer are blind (double blind).Outcome elevator and analyzer don't aware from grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committe Arak University Of Medical Sciences
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code

848176941

Approval date
2018-01-21, 1396/11/01

Ethics committee reference number
IR.ARAKMU.REC.1396.267

Health conditions studied

1

Description of health condition studied

Craniotomy

ICD-10 code

S00

ICD-10 code description

Superficial injury of head

Primary outcomes

1

Description

Heart rate

Timepoint

Every 15 minutes until the end of surgery

Method of measurement

Count

2

Description

Blood pressure

Timepoint

Every 15 minutes until the end of surgery

Method of measurement

Barometer

3

Description

Bleeding

Timepoint

Every 15 minutes until the end of surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We inject 1 milligram in kilogram Dexmedetomidin in Dexmedetomidin group as loading dose and after Intubation we inject 0/5 milligram in kilogram in hours Dexmedetomidin infusion.

Category

Treatment - Drugs

2

Description

Intervention group: We inject 1 milligram in kilogram osmolol in 10 milliliter normal saline in osmolol group as loading dose and after Intubation we inject 0/5 milligram in kilogram in hours osmolol infusion.

Category

Treatment - Drugs

3

Description

Intervention group: We inject 50 milligram in kilogram in 100 milliliter normal saline as loading dose and after Intubation we inject 15 milligram in kilogram in hours magnesium sulfate 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, Arak

City

Arak

Province

Markazi

Postal code

848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alikamaliir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, 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

848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

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

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 Alireza Kamali

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alikamaliir@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
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Valiasr Hospital, Valiasr square, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
alikalim@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Farsi
Position
Student of medicine
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Payambar Azam Complex, Basij square, Sardasht,
Arak
City
Arak
Province

Markazi
Postal code
848176941
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
alirezafarsi2004@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Alireza Kamali

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments