

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effect of local infiltration of Ropivacaine on hemodynamic status during the craniotomy on patients at the Khorramabad Shohada Ashayer hospital

Protocol summary

Summary

This study is a clinical trial. Study population are patients under craniotomy in in the Khorramabad Shohada hospital with using general anesthesia. Patients were randomly divided into two groups: case and control. Patients are matched by age and gender. After monitoring between 3-5 minutes before induction, intravenous midazolam and fentanyl intravenously at a dose of 0.06mg/kg 3µg/kg, respectively, and Nesdonal at a dose of 5mg/kg and atracurium at dose 0.5mg/kg is administered to the patients. After 3-4 min laryngoscopy is done and tracheal tube fixed. Isoflurane gas is open with amount 1-1.5 percent. The systolic, diastolic and mean arterial blood pressure and heart rate are measured. 7-10 min after fixation of tracheal tube the four item were measured. At the incision place in the case group, 10 ml of 0.5% Ropivacaine is topical infiltration. 30 seconds, 1, 3, 5 and 10 min after incision the four item were measures. At the end of surgery amount of drug and isoflurane gas are used is recorded. In the control group of normal saline solution in the same position and the same amount used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050316066N4**
Registration date: **2014-05-28, 1393/03/07**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-28, 1393/03/07

Registrant information

Name

Siavash Beiranvand

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 66 1221 5006

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Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2013-12-01, 1392/09/10

Expected recruitment end date

2014-01-30, 1392/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of local infiltration of Ropivacaine on hemodynamic status during the craniotomy on patients at the Khorramabad Shohada Ashayer hospital

Public title

Evaluation of the effect of local infiltration of Ropivacaine on hemodynamic status during the craniotomy on patients at the Khorramabad Shohada Ashayer hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: absence of underlying renal, hepatic,

and consent to participate in the study. Exclusion criteria: not thrilled inclusion criteria and having a history of drug allergy .

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Lorestan University of Medical Sciences

Street address

Pardis Academic Complex

City

Khorramabad

Postal code

381351698

Approval date

2013-11-30, 1392/09/09

Ethics committee reference number

200/96196

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

Patients undergoing craniotomy with general anesthesia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

vital sign(The systolic, diastolic and mean arterial blood pressure and heart rate)

Timepoint

vital sign(The systolic, diastolic and mean arterial blood pressure and heart rate):after intubation and 7-10 min after intubation and 30 second and 1,3,5,10 min after incision

Method of measurement

The systolic, diastolic and mean arterial blood pressure:mmHg,monitoring.Heart Rate:frequency.monitoring

2**Description**

Narcotic drug

Timepoint

the end of surgery

Method of measurement

gram

3**Description**

Isoflorane gas

Timepoint

the end of surgery

Method of measurement

%

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Ropivacaine 0.5%, 1 ml in incision place (before incision), local infiltration

Category

Other

2**Description**

Control group: normal saline solution; 1 ml in incision place (before incision), local infiltration

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada Ashayer Hospital

Full name of responsible person

Dr Siavash Beiranvand

Street address

Enqelab st.Shohada Ashayer Hospital

City
Khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Lorestan University of Medical Sciences (Assistance of research & technology)
Full name of responsible person
Dr Mohamad Hasan Kayedi
Street address
Kamalvand Medical Science university
City
Khorramabad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Lorestan University of Medical Sciences (Assistance of research & technology)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Lorestan University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty