

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The impact of subcutaneous infiltration of 0.5% bupivacaïen on the c-reactive protein titer and hemodynamic parameters after craniotomy

Protocol summary

Summary

Patients who were schedule for elective craniotomy for intracranial tumors surgeries and aged between 18 to 65 yr enrolled in this study. Patients who had history of head trauma, previous craniotomy, documented allergy to bupivacaine and uncontrolled hypertension were excluded from the study. Patients were enrolled to receive either 20 ml of 0.25% bopivacaine(intervention group) or 20 ml of 0.9% normal saline(control group). Before the induction of general anesthesia, standard monitoring consisted of electrocardiography, heart rate, pulse oximetry, systolic BP, diastolic BP, and mean arterial pressure (MAP) were performed. An arterial catheter was inserted into right radial artery for BP monitoring and blood sampling.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111138087N1**

Registration date: **2011-12-01, 1390/09/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-01, 1390/09/10

Registrant information

Name

Saber Aminzadeh

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 918 332 3402

Email address

aminzadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-10, 1390/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of subcutaneous infiltration of 0.5% bupivacaïen on the c-reactive protein titer and hemodynamic parameters after craniotomy

Public title

The impact of subcutaneous infiltration of 0.5% bupivacaïen on the c-reactive protein titer and hemodynamic parameters after craniotomy

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:being candidate for craniotomy and age between18 to 65 years. Exclusion criteria: need for emergency surgery ; previous craniotomy and Diabetes Melitus

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of Medical Sciences

Street address

Sixth floor, Main building of Tehran University of Medical Sciences, Keshavarz blv.

City

Tehran

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

686

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

Craniotomy

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

Heart Rate

Timepoint

Before, 1,5,10 and 15 minutes after surgery

Method of measurement

Objective Record

2**Description**

C-reactive protein

Timepoint

Before surgery, 24 and 48 Hours after surgery

Method of measurement

Plasma Sample

3**Description**

Mean Arterial Pressure

Timepoint

Before, 1, 5, 10 and 15 minutes after surgery

Method of measurement

Objective Record

Secondary outcomes**1****Description**

Tachycardia

Timepoint

Before surgery, 1; 5 10 and 15 minutes after surgery

Method of measurement

Objective Record

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

Subcutaneous injection of 20 ml 0.9% normal saline

Category

Placebo

2**Description**

Subcutaneous Injection of Bupivacaine 25%

Category

Treatment - Drugs

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

Sina Hospital

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran university of medical sciences

Full name of responsible person

Reza Moharer shariate
Street address
Tehran university of medical sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran university of medical sciences
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
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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