

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Effect of Scalp Infiltration with Bupivacaine Compared with Intravenous Morphine on the postoperative pain of patients undergoing craniotomy

#### Protocol summary

##### Summary

Objectives: Determine the effect of topical Bupivacain on pain in patients undergoing craniotomy with intravenous morphin Design: Interventional, Double blinded, Patient and investigators have been unaware. Major Inclusion criteria: More than 18 years of age; Undergoing elective supratentorial craniotomy surgery under general anaesthesia due to tumors or vascular lesions. Major exclusion criteria: Coronary artery disease with a contraindication to epinephrine administration; Pain due to intracranial pathology, not differentiated from post-operative pain; Addiction to alcohol and drugs; Active psychiatric illness; Chronic pain after more than 2 weeks drug use; Positive history of migraine headaches; Patient's inability to understand or answer numeric response questions; Confirmed or potential sensitivity to topical anaesthesia; probable need for post-operative mechanical ventilation; Previous craniotomy or history of radiotherapy of the head; Pregnancy. Intervention group: Bupivacaine 0.25% maximum dose of 2 mg per kilogram of patient weight Control group: Morphine 0.1 mg per kg of body weight Primary outcome measure: Patient's pain after surgery, 2, 4, 6, 8, 12 and 24 hours after surgery by Pain Scale Visual

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014012513307N2**  
Registration date: **2014-02-20, 1392/12/01**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-02-20, 1392/12/01

#### Registrant information

##### Name

Fariba Hushmandi

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1846 5779

##### Email address

houshmandif881@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

#### Expected recruitment start date

2012-03-04, 1390/12/14

#### Expected recruitment end date

2013-02-19, 1391/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of Scalp Infiltration with Bupivacaine Compared with Intravenous Morphine on the postoperative pain of patients undergoing craniotomy

#### Public title

Determine the effect of topical Bupivacaine on pain of patients undergoing craniotomy

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Major Inclusion criteria: More than 18 years of age; Undergoing elective supratentorial craniotomy surgery

under general anaesthesia due to tumors or vascular lesions. Major exclusion criteria: Coronary artery disease with a contraindication to epinephrine administration; Pain due to intracranial pathology, not differentiated from post-operative pain; Addiction to alcohol and drugs; Active psychiatric illness; Chronic pain after more than 2 weeks drug use; Positive history of migraine headaches; Patient's inability to understand or answer numeric response questions; Confirmed or potential sensitivity to topical anaesthesia; probable need for post-operative mechanical ventilation; Previous craniotomy or history of radiotherapy of the head; Pregnancy.

#### Age

From **18 years** old to **149 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **68**

#### 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

Ethics Committee of Mashhad University of Medical Sciences

###### Street address

Vice Chancellor for Research of Mashhad University of Medical Sciences, Ghoreishi Building, Daneshgah Street, Mashhad

###### City

Mashhad

###### Postal code

91375-345

##### Approval date

2012-03-03, 1390/12/13

##### Ethics committee reference number

2083226

### Health conditions studied

#### 1

##### Description of health condition studied

Pain after surgery

##### ICD-10 code

R52.9

##### ICD-10 code description

Pain, unspecified

### Primary outcomes

#### 1

##### Description

Patient's pain after surgery

##### Timepoint

2, 4, 6, 8, 12 and 24 hours after surgery

##### Method of measurement

Pain Scale Visual

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Bupivacaine 0.25% maximum dose of 2 mg per kilogram of patient weight

##### Category

Prevention

#### 2

##### Description

Control group: Morphine 0.1 mg per kg of body weight

##### Category

Prevention

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Ghaem Hospital

###### Full name of responsible person

Fariba Houshmandi

###### Street address

Ghaem Hospital, Ahmadabbad Avenue, Mashhad

###### City

Mashhad

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Vice Chancellor for Research of Mashhad University of

Medical Sciences

**Full name of responsible person**

Faribe Houshmandi

**Street address**

Vice Chancellor for Research of Mashhad University of  
Medical Sciences, Ghoreishi Building, Daneshgah  
Street, Mashhad

**City**

Mashhad

**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 of Mashhad 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**

Ghaem Hospital

**Full name of responsible person**

Fariba Houshmandi

**Position**

Student

**Other areas of specialty/work**

**Street address**

Neurology Department, Ghaem Hospital, Ahmad Abad  
Avenue, Mashhad

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## Person responsible for scientific inquiries

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Associate Professor

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## Person responsible for updating data

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**Position**

Student

**Other areas of specialty/work**

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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*