Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 intravenouse 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

City

Mashhad

Postal code

Phone

+98 51 1846 5779

Fax

Email

houshmandif881@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghaem Hospital

Full name of responsible person

Hossein Mashhadi Nazar

Position

Associate Professor

Other areas of specialty/work

Street address

Ghaem Hospital, Ahmadabad Avenue, Mashhad

City

Mashhad

Postal code

Phone

+98 51 1840 2205

Fax

Email

mashhadinejadh@mums.ac.ir

Web page address

Person responsible for updating data

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

City

Mashhad

Postal code

Phone

+98 51 1846 5779

Fax

Email

houshmandif881@mums.ac.

Web page address

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