Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the efficacy of Craniotomy and Duraplasty versus Craniotomy, lobectomy and duraplasty Operations in acute traumatic subdural hematoma

Protocol summary

Summary

Background: Acute traumatic subdural hematoma represents a cause of permanent disability and mortality rate in the adult population. The aim of this study is to comparative outcomes of craniotomy and duraplasty versus craniotomy, duraplasty and lobectomy operations in patients with acute traumatic subdural hematoma. Methods: patients with traumatic subdural hematoma are divided randomly who underwent surgical treatment, Craniotomy & Duraplasty (Group I), and Craniotomy, Duraplasty and Lobectomy (Group II). For all patients, Glasgow coma scale (GCS) before surgery and Glasgow Outcome Scale (GOS) after three months of surgery will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051313307N1**
Registration date: **2013-05-26, 1392/03/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-05-26, 1392/03/05

Registrant information

Name

Fariba Hushmandi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2012-01-18, 1390/10/28

Expected recruitment end date

2013-08-11, 1392/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of Craniotomy and Duraplasty versus Craniotomy, lobectomy and duraplasty Operations in acute traumatic subdural hematoma

Public title

Craniotomy and Duraplasty versus Craniotomy, lobectomy and duraplasty Operations in sever head trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients higher than 18 years old, with traumatic subdural hematoma; patients with intracranial hypertension evidence, and patients with Glasgow outcome score (GCS) lower or equal to 8 before surgery. Exclusion criteria: patients with peripheral or central neuropathy before surgery; patients with metabolic syndrome.

Age

From **18 years** old to **90 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashad University of Medical Sciences

Street address
Central Building of Mashad University of Medical Sciences

City
Mashhad

Postal code

Approval date
2011-02-11, 1389/11/22

Ethics committee reference number
631827

Health conditions studied

1

Description of health condition studied
traumatic subdural hematoma

ICD-10 code
S06.5

ICD-10 code description
Traumatic subdural haemorrhage

Primary outcomes

1

Description
Glasgow coma scale

Timepoint
pre and post operative evaluation

Method of measurement
Assessment of awareness by Glasgow coma scale questionnaire

Secondary outcomes

1

Description
Mortality rate and Glasgow Outcome Scale

Timepoint
3 months after surgery

Method of measurement
Assay the mortality and disability after operation by Glasgow Outcome Scale questionnaire

Intervention groups

1

Description
Group II: Craniotomy, Duraplasty and Lobectomy operations

Category
Treatment - Surgery

2

Description
Group I: Craniotomy and Duraplasty operations

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Kamyab Hospital

Full name of responsible person

Street address

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Council of Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohsen Tafaghodi

Street address
Central Building of Mashad University of Medical Sciences

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Fariba Housmandi

Position

Anesthesiology resident

Other areas of specialty/work

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Position

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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