

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

A randomized controlled trial to compare the effect of endoscopic third ventriculostomy versus ventriculoperitoneal shunt insertion in infants less than one year of age with obstructive hydrocephalus

Protocol summary

Summary

Objective: comparison of the efficacy of ETV versus VP shunt in infants less than one year of age with obstructive hydrocephalus Study design: Randomized, two armed, unblind, parallel active control, single center, phase 2-3 Study population: infants less than 1 year of age with obstructive hydrocephalus without any previous intervention or active infection Sample size: 50 patients (25 in each arm) Primary outcome: Absence of abnormal increase in head circumference and absence of rICP signs

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020416483N1**
Registration date: **2016-04-18, 1395/01/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-18, 1395/01/30

Registrant information

Name

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Name of organization / entity

Tehran University of Medical Sciences, Shariati Hospital

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences Thesis Grant

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized controlled trial to compare the effect of endoscopic third ventriculostomy versus ventriculoperitoneal shunt insertion in infants less than one year of age with obstructive hydrocephalus

Public title

Comparison of the results of ventriculoperitoneal shunt insertion and Endoscopic Third Ventriculostomy in obstructive hydrocephalus in infants less one year in children medical center hospital between 2013-2016

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All infants less than 1 year of age with obstructive hydrocephalus without any previous intervention for treatment of hydrocephalus Exclusion criteria: 1. Presence of active infection 2. Parent of legal guardian discontent to sign the informed consent form

Age

To **1 year** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

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 Tehran University of Medical Sciences

Street address

Ghods Street, Central office of Tehran University of Medical Sciences

City

Tehran

Postal code**Approval date**

2015-05-05, 1394/02/15

Ethics committee reference number

9011255002-140438

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

Obstructive hydrocephalus

ICD-10 code

G91.1

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

Absence of abnormal increase in head circumference

Timepoint

6 months

Method of measurement

Clinical examination and Imaging

2**Description**

bsence of raised intracranial pressure (rICP) signs

Timepoint

6 months

Method of measurement

Clinical examination and Imaging

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

CSF leakage

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination and Imaging

2**Description**

Wound dehiscence

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination

3**Description**

Bleeding

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination and Imaging

4**Description**

Temporary ICP Rising

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination and Imaging

5**Description**

Requiring ETV reoperation

Timepoint

Monthly

Method of measurement

Clinical examination and Imaging

6**Description**

Requiring VP shunt

Timepoint

Monthly

Method of measurement

Clinical examination and Imaging

7

Description

Permanent ICP Rising

Timepoint

Monthly

Method of measurement

Clinical examination and Imaging

8

Description

EVD

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination and Imaging

9

Description

Shunt exposure

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination

10

Description

Obstruction of shunt proximal end

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination and Imaging

11

Description

Abdominal pseudocyst

Timepoint

Monthly

Method of measurement

Clinical examination and Imaging

12

Description

Infection

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination

13

Description

Meningitis

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination

14

Description

Subdural hematoma

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination and Imaging

15

Description

CSF collection

Timepoint

Daily for 7 days and then monthly

Method of measurement

Clinical examination

16

Description

Shunt dehiscence

Timepoint

Daily for 7 days and then monthly

Method of measurement

Imaging

Intervention groups

1

Description

Endoscopic third ventriculostomy

Category

Treatment - Surgery

2

Description

Ventriculoperitoneal Shunt

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Center Hospital

Full name of responsible person

Dr Amir Amini Navai

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of medical sciences

Full name of responsible person

Dr Farideh Nejat

Street address

Ghods Street, Central office of 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

Department of neurosurgery, Shariati Hospital,
Tehran university of medical sciences, Tehran, Iran

Full name of responsible person

Dr Amir Amini Navai

Position

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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