

# 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

Amir Amininavai

##### Name of organization / entity

Tehran University of Medical Sciences, Shariati Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8490 2384

##### Email address

amininavai.a@shariatihospital.ir

##### 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**

Absence 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**

Resident of neurosurgery

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

**Contact**

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Professor of Neurosurgery

**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

Resident of neurosurgery

**Other areas of specialty/work**

**Street address**

Kargar street, Shariati hospital

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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*