

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of endoscopic third ventriculostomy in the treatment and prevention of obstructive hydrocephalus in patients with posterior fossa tumors of the brain in patients referred to the hospital

Protocol summary

Study aim

The effect of endoscopic third ventriculostomy in the treatment and prevention of obstructive hydrocephalus in patients with posterior fossa tumors of the brain in patients referred to the hospital

Design

The design of the study is a randomized clinical trial. The randomization method is blocked. The sample size for each study group is 20.

Settings and conduct

In this research, all patients referred to the Hazrat Rasoul Akram Hospital, who have posterior fossa tumors of the brain will be enrolled. Patients will be randomly divided into two groups based on 4 blocks. A total of 40 patients will be examined. Data analyzers will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients referred to Rasoul Akram Hospital, who have posterior fossa tumors of the brain will be enrolled. All patients with tumorous lesions of the posterior fossa of the brain with obstructive hydrocephalus. Exclusion criteria: Patients who had a recurrence of the tumor.

Intervention groups

In the intervention group, For patients with posterior fossa tumors of the brain the endoscopic third ventriculostomy will be performed. In the control group: For patients with posterior fossa tumors of the brain, a brain shunt will be placed.

Main outcome variables

Intra brain pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171124037606N3**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **prospective**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

Registration date

2019-03-10, 1397/12/19

Registrant information

Name

Alireza Tabibkhoei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2228

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of endoscopic third ventriculostomy in the treatment and prevention of obstructive hydrocephalus in patients with posterior fossa tumors of the brain in patients referred to the hospital

Public title

Endoscopic third ventriculostomy in the treatment and prevention of hydrocephalus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with tumorous lesions of the posterior fossa of the brain with obstructive hydrocephalus

Exclusion criteria:

Patients who had a recurrence of the tumor

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks with 4 person. In each block, 2 individuals will be in intervention group and 2 will be in control group. A total of 10 blocks will be considered for sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data will be analyzed by person who is blind to study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-11-13, 1396/08/22

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9411255004

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

Obstructive hydrocephalus

ICD-10 code

G91.1

ICD-10 code description

Obstructive hydrocephalus

Primary outcomes**1****Description**

Intra brain pressure

Timepoint

One week continuously (24 hour)

Method of measurement

Using ICP monitoring

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For patients with posterior fossa tumors of the brain, the endoscopic third ventriculostomy will be performed.

Category

Treatment - Surgery

2**Description**

Control group: For patients with posterior fossa tumors of the brain, a brain shunt will be placed.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hazrat Rasoul Akram hospital

Full name of responsible person

Alireza Tabibkhoei

Street address

Hazrate Rasool hospital, Niyayesh street, Sattarkhan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kazem Malakooti
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Javid Jahandideh
Position
Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

Specialist

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available