

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating the effect of Acetazolamide administration and prone positioning following lumbosacral spinal surgery in preventing cerebrospinal fluid leak and collection and wound dehiscence

Protocol summary

2013-04-24, 1392/02/04

Summary

Purpose of study: to determine the preventive effect of acetazolamide administration, prone positioning, and the combination of both following the neurosurgical interventions in lumbosacral region for CSF leak, CSF collection and wound dehiscence. Primary inclusion criteria: if these patients underwent untethering surgery due to primary tethered cord syndrome, resection of lipoma, lipomyelomeningocele, split cord malformation management, tumors with intradural management or having any other disease with similar management technique due to the opinion of the surgeon, they will be included. Primary exclusion criteria: patients with diagnosis of myelomeningocele, meningocele, infected dermoid cysts, intramedullary abscess, presence of hydrocephalus and those who underwent reoperation will be excluded from this study. Sample size: 144 Group A: Acetazolamide administration for 10 days Group B: prone positioning for 10 days Group C: Acetazolamide administration+ prone positioning for 10 days Group D: no intervention Period of study: Autumn 2012 to the end of winter of 2014 Outcomes: (CSF leak, CSF collection, wound dehiscence) rate following (Acetazolamide administration, prone positioning, Acetazolamide administration+ prone positioning) for 10 days

Registrant information

Name

Shima Shahjouei

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences,

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Acetazolamide administration and prone positioning following lumbosacral spinal surgery in preventing cerebrospinal fluid leak and collection and wound dehiscence

Public title

Factors affecting the outcome of Lumbosacral Spinal Surgery

Purpose

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100611023N1**

Registration date: **2013-04-24, 1392/02/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Prevention

Inclusion/Exclusion criteria

The patients visiting the neurosurgery clinic of children`s medical center hospital during Autumn 2012 to the end of winter of 2015 who need lumbosacral surgery will be screened. If these patients underwent unthetering surgery due to primary tethered cord syndrome, resection of lipoma, lipomyelomeningocele, split cord malformation management, tumors with intradural management or having any other disease with similar management technique due to the opinion of the surgeon, they will be included. Patients with diagnosis of myelomeningocele, meningocele, infected dermoid cysts, intramedullary abscess, presence of hydrocephalus and those who underwent reoperation will be excluded from this study.

Age

To **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical ethics and history of medicine research center of Tehran University of Medical Sciences

Street address

4th Floor, No. 23, before Pour Sina St. - 16th Azad St. - Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2012-12-04, 1391/09/14

Ethics committee reference number

2137

Health conditions studied

1

Description of health condition studied

Tethered cord- split cord malformation

ICD-10 code

G93.9

ICD-10 code description

Disorder of brain, unspecified

2

Description of health condition studied

Lipomyelomeningocele

ICD-10 code

D17.9

ICD-10 code description

Benign lipomatous neoplasm, unspecified

Primary outcomes

1

Description

Cerebrospinal fluid leakage

Timepoint

1month

Method of measurement

specialist opinion

2

Description

Cerebrospinal fluid collection

Timepoint

1 month

Method of measurement

specialist opinion

3

Description

wound dehiscence

Timepoint

1 month

Method of measurement

specialist opinion

Secondary outcomes

empty

Intervention groups

1

Description

Group A: Acetazolamide administration (as tablet or solved in water, dosage depending on the weight of the child) for 10 days

Category

Prevention

2

Description

Group C: Acetazolamide administration(as tablet or solved in water, dosage depending on the weight of the child) for 10 days+ prone positioning for 10 days

Category

Prevention

3

Description

Group B: prone positioning for 10 days

Category

Prevention

4

Description

Group D: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Children`s Medical Center

Full name of responsible person

Shima Shahjouei

Street address

Children's Medical Center, 62 Qarib St. , Keshavarz Blvd., Tehran 14194, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shaahin akhoondzadeh

Street address

No 206, Flat 1, Building no 1, Medicine Faculty,
Poursina st., Keshavarz blv., Tehran, Iran

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

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Farideh Nejat

Position

Professor

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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