Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating the effect of Acetazolamide adminestration and prone positioning following lumbosacral spinal surgery in preventing cerebro spinal fluid leak and collection and wound dehissence

Protocol summary

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

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

2013-04-24, 1392/02/04

Registrant information

Name
Shima Shahjouei
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8825 6697
Email address
shimashah@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sceineces,

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 adminestration and prone positioning following lumbosacral spinal surgery in preventing cerebro spinal fluid leak and collection and wound dehissence

Public title

Factors affecting the outcome of Lumbosacral Spinal Surgery

Purpose

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 underwernt 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
Shima Shahjouei
Position
Student
Other areas of specialty/work
Street address
Iran, Tehran, Poursina st., Keshavarz blv., Tehran University of Medical Sciences
City
Tehran
Postal code
Phone
+98 21 8825 6697
Fax
Email
shimashah@student.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Farideh Nejat
Position
Professor
Other areas of specialty/work
Street address
Poursina st., Keshavarz blv.
City
Tehran
Postal code
Phone
+98 66420098
Fax
Email
nejat@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Shima Shahjouei
Position
Student
Other areas of specialty/work
Street address
Flat3, No 9th, 16th St., Gisha st., Tehran, Iran
City
Tehran
Postal code
Phone
+98 88256697
Fax
Email
shimashah@student.tums.ac.ir
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