Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of acetazolamide efficacy in preventing CSF leak after dural repair post spinal surgery

Protocol summary

Summary

Cerebrospinal fluid leak is known to be one of the side effects of spinal surgery. This usually happens when intra-dural lesions like spinal tumors andintra-spinal hemorrhage undergo surgery. In some cases, dura tear happen in trauma incidences. Due to risks of CSF leakage, prevention is essential. Acetazolamide is a carbonic-anhydraze inhibitor (a diuretic agent) which has been long used to prevent the leak, however, very few literature is available on the efficacy of this medicine. The present study will try to address this knowledge gap using a double blind randomized controlled trial comparing oral acetazolamide plus corrected body position versus corrected body position alone. Patients (n=70) undergoing spinal surgery with dura damage will be included in the study and CSF leak will be assessed as the primary outcome of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501178612N2**
Registration date: **2015-06-10, 1394/03/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-10, 1394/03/20

Registrant information

Name

Amir Sarayani

Name of organization / entity

Research Center for Rational Use of Drugs

Country

Iran (Islamic Republic of)

Phone

+98 21 8881 4157

Email address

a-sarayanib@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Pharmaceutical care department-Shariati hospital

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of acetazolamide efficacy in preventing CSF leak after dural repair post spinal surgery

Public title

Effect of acetazolamide on the prevention of cerebrospinal fluid leakage after spinal surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: Dura tear during spinal surgery; Intra-dural tumor; trauma-related dura tear Exclusion: previous surgery and dura tear in the same location; history of chemotherapy or radiotherapy; malnutrition; uncontrolled metabolic disease

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz Blvd

City

Tehran

Postal code

Approval date

2014-08-31, 1393/06/09

Ethics committee reference number

93-1144-130-ص

Health conditions studied

1

Description of health condition studied

Dura damage

ICD-10 code

G97.0

ICD-10 code description

Cerebrospinal fluid leak from spinal puncture

Primary outcomes

1

Description

CSF leakage

Timepoint

Daily until 8 weeks post discharge

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: 1. Acetazolamide oral tablet; 20 mg/kg/day in 3-4 daily doses for 7 days post surgery 2. Patient in position 3/4 lateral

Category

Treatment - Drugs

2

Description

Control: 1. Patient in position 3/4 lateral

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Alireza Khoshnevisan MD

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharmaceutical care department-Shariati Hospital

Full name of responsible person

Mohammadreza Javadi

Street address

Jalal-Al-Ahmad Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pharmaceutical care department-Shariati Hospital

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

Shariati Hospital

Full name of responsible person

Elham Amini PharmD

Position

Pharmacist, Pharmaceutical care department/Neurosurgery department

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shariati hospital

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 updating data

Contact

Name of organization / entity

Research Center for Rational Use of Drugs

Full name of responsible person

Amir Sarayani PharmD

Position

PharmD, MPH

Other areas of specialty/work

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a-sarayanib@razi.tums.ac.ir

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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