

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of efficacy of prophylactic antibiotic therapy in prevention of incidence of meningitis in patient with basilar skull fracture and cerebrospinal fluid leakage in traumatic patient refer to golestan hospital of ahvaz in 2014-2015

Protocol summary

Summary

Patients with traumatic base skull fractures with cerebrospinal fluid leakage were selected. All participants underwent CT scans upon arrival. Patients with visible lesions on CT scans in need of surgery for example Depress skull fracture, space occupying lesions, signs of intracranial pressure increase excluded. At least 350 patient selected. Then placebo drugs with complete resemblance to cotrimoxazole and amoxicillin provided. These drugs were placed in two boxes, box A and box B, and offered to patients as ordered by the physician. All patients received standard conservative treatment and lumbar punctures were performed during the first three days of admission. All patients with cerebrospinal fluid disturbance and meningitis were excluded from the study. Patients were divided into two groups. In the treatment group, patients were given prophylactic antibiotics along with oral cotrimoxazole and amoxicillin. In the control group, patients received standard conservative treatment along with placebo drugs. In cases with cerebrospinal fluid leakage for over 3 days, a lumbar puncture was repeated or lumbar drain was placed. In cases with signs of meningitis such as fever, purulent discharge, meningismus excluded from study. Another lumbar puncture was performed after ceasing of cerebrospinal fluid leakage and before discharge in the other patients. Patients were examined for headaches and signs of meningitis in their first follow up visit after release. Finally, evaluate efficacy of prophylactic antibiotic in prevention of morbidity and mortality of meningitis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014123020485N1**

Registration date: **2015-05-25, 1394/03/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-25, 1394/03/04

Registrant information

Name

Hasan Akbardokht

Name of organization / entity

Ahvaz Jundi Shapur Medical Science University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-02-08, 1393/11/19

Expected recruitment end date

2015-06-19, 1394/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of prophylactic antibiotic therapy in prevention of incidence of meningitis in patient with basilar skull fracture and cerebrospinal fluid leakage in traumatic patient refer to golestan hospital of ahvaz in 2014-2015		Approval date 2015-02-07, 1393/11/18
		Ethics committee reference number ajums.rec.1393.398
Public title Evaluation of efficacy of prophylactic antibiotic therapy in prevention of incidence of meningitis in patient with basilar skull fracture and cerebrospinal fluid leakage	Health conditions studied	
Purpose Prevention	1	
Inclusion/Exclusion criteria (Inclusion criteria:Selected patients suffered from traumatic base skull fractures with cerebrospinal fluid leakage characterized by rhinorrhea or otorrhea;All participants were at least 18 years old) (Exclusion criteria: Patients with visible lesions on CT scans in need of surgery;patient with Depressed skull fracture, space-occupying lesions, signs of intracranial pressure increase;patients with cerebrospinal fluid disturbance and/ or meningitis; In cases with signs of meningitis such as fever, purulent discharge, meningismus)	Description of health condition studied Fracture of base of skull due to trauma	
	ICD-10 code S02.1	
	ICD-10 code description Fracture of base of skull	
Age From 18 years old to 80 years old	Primary outcomes	
Gender Both	1	
Phase N/A	Description Prevention of incidence of meningitis in patient with basilar skull fracture and csf leakage	
Groups that have been masked <i>No information</i>	Timepoint TBI patient refer to Golestan hospital of ahvaz in 2014-2015	
Sample size Target sample size: 346	Method of measurement Analyse of csf obtain from lumbar puncture	
Randomization (investigator's opinion) Randomized	Secondary outcomes	
Randomization description	1	
Blinding (investigator's opinion) Double blinded	Description incidence of meningitis	
Blinding description	Timepoint in course of admission	
Placebo Used	Method of measurement with lumbar puncture and analyse of cerebrospinal fluid sample	
Assignment Parallel	Intervention groups	
Other design features	1	
Secondary Ids empty	Description Approximately 178 patients with CSF leak following base skull fractures were selected. For prophylaxis, two Cotrimoxazole tablets (400/80 miligram) and three Amoxicillin capsules (500 miligram) were administered daily.	
Ethics committees	Category Prevention	
1	2	
Ethics committee	Description In the control group, placebo drugs with complete resemblance to the actual drugs were given to patients (two Cotrimoxazole placebo tablets and three Amoxicillin placebo capsules, daily). The placebo drugs were	
Name of ethics committee Ahvaz Jondi Shapour University of Medical Sciences		
Street address Ahvaz medical science university-Golestan-Ahvaz		
City Ahvaz		
Postal code 61357-15794		

provided by Ahvaz Jundishapour Medical Universities
School of Pharmacy.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapour Medical University

Full name of responsible person

Dr Akbardokht- Dr Bahrami

Street address

Golestan hospital-Neurosurgery ward

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapour Medical University

Full name of responsible person

Dr Hasan Akbardokht

Street address

Neurosurgery ward-Ahvaz Golestan hospital

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapour Medical University

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

Ahvaz Jundishapour Medical Sciences University

Full name of responsible person

Dr Hasan Akbardokht

Position

MD- resident of neurosurgery

Other areas of specialty/work

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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