

# 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

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###### Name of organization / entity

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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 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Approval date</b><br>2015-02-07, 1393/11/18                                                                                                                                                                                                   |
|                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Ethics committee reference number</b><br>ajums.rec.1393.398                                                                                                                                                                                   |
| <b>Public title</b>                                                                                                                                                                                                                             | Evaluation of efficacy of prophylactic antibiotic therapy in prevention of incidence of meningitis in patient with basilar skull fracture and cerebrospinal fluid leakage                                                                                                                                                                                                                                                                                                                                                                              | <b>Health conditions studied</b>                                                                                                                                                                                                                 |
| <b>Purpose</b>                                                                                                                                                                                                                                  | Prevention                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>1</b>                                                                                                                                                                                                                                         |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                             | (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) | <b>Description of health condition studied</b><br>Fracture of base of skull due to trauma                                                                                                                                                        |
| <b>Age</b>                                                                                                                                                                                                                                      | From <b>18 years</b> old to <b>80 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>ICD-10 code</b><br>S02.1                                                                                                                                                                                                                      |
| <b>Gender</b>                                                                                                                                                                                                                                   | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>ICD-10 code description</b><br>Fracture of base of skull                                                                                                                                                                                      |
| <b>Phase</b>                                                                                                                                                                                                                                    | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Primary outcomes</b>                                                                                                                                                                                                                          |
| <b>Groups that have been masked</b>                                                                                                                                                                                                             | No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>1</b>                                                                                                                                                                                                                                         |
| <b>Sample size</b>                                                                                                                                                                                                                              | Target sample size: <b>346</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Description</b><br>Prevention of incidence of meningitis in patient with basilar skull fracture and csf leakage                                                                                                                               |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                                                                   | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Timepoint</b><br>TBI patient refer to Golestan hospital of ahvaz in 2014-2015                                                                                                                                                                 |
| <b>Randomization description</b>                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Method of measurement</b><br>Analyse of csf obtain from lumbar puncture                                                                                                                                                                       |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                                                                        | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Secondary outcomes</b>                                                                                                                                                                                                                        |
| <b>Blinding description</b>                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>1</b>                                                                                                                                                                                                                                         |
| <b>Placebo</b>                                                                                                                                                                                                                                  | Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Description</b><br>incidence of meningitis                                                                                                                                                                                                    |
| <b>Assignment</b>                                                                                                                                                                                                                               | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Timepoint</b><br>in course of admission                                                                                                                                                                                                       |
| <b>Other design features</b>                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Method of measurement</b><br>with lumbar puncture and analyse of cerebrospinal fluid sample                                                                                                                                                   |
| <b>Secondary Ids</b>                                                                                                                                                                                                                            | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Intervention groups</b>                                                                                                                                                                                                                       |
| <b>Ethics committees</b>                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>1</b>                                                                                                                                                                                                                                         |
| <b>1</b>                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Description</b><br>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. |
| <b>Ethics committee</b>                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Category</b><br>Prevention                                                                                                                                                                                                                    |
| <b>Name of ethics committee</b>                                                                                                                                                                                                                 | Ahvaz Jondi Shapour University of Medical Sciences                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>2</b>                                                                                                                                                                                                                                         |
| <b>Street address</b>                                                                                                                                                                                                                           | Ahvaz medical science university-Golestan-Ahvaz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Description</b><br>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         |
| <b>City</b>                                                                                                                                                                                                                                     | Ahvaz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                  |
| <b>Postal code</b>                                                                                                                                                                                                                              | 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**

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**Full name of responsible person**

Dr Hasan Akbardokht

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**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*