ISRCTN71132784 https://doi.org/10.1186/ISRCTN71132784

Prophylactic antibiotics for the prevention of meningitis after traumatic pneumocephalus

Submission date	Recruitment status
02/03/2005	No longer recruiting
Registration date	**Overall study status**
11/03/2005	Completed
Last Edited	**Condition category**
20/09/2017	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prophylactic antibiotics for the prevention of meningitis after traumatic pneumocephalus: a randomised controlled trial

Study objectives
Chemoprophylaxis with antibiotics is both feasible and desirable for prevention of a potentially serious disease when specific groups at risk can be defined and when a safe, effective, and affordable prophylactic agent is available. One of such potentially serious diseases is post-traumatic meningitis. The incidence of post-traumatic meningitis after head trauma ranges from 0.2 to 17.8 per cent and increases significantly in the presence of skull base fracture, pneumocephalus or cerebrospinal fluid (CSF) leak.

Considering the serious complications of the post-traumatic meningitis, the idea of chemoprophylaxis with antibiotics for prevention of post-traumatic meningitis has always been considered rational, but the efficacy of prophylactic antibiotic agents in the setting of post-traumatic CSF leakage is still controversial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study has been ethically approved by Sina Trauma and Surgery Research Center, Tehran University.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Traumatic pneumocephalus (entrance of air into the cranium after head trauma)

Interventions

The patients are divided into three groups:
1. Intravenous antibiotics (IV)
2. Oral antibiotics (O)
3. Placebo (P)

In the IV group, ceftriaxone 2 g twice daily (BID) plus oral placebo will be given and in the O group, azithromycin 500 mg in the first day followed by 250 mg daily plus intravenous placebo for the rest will be continued for 7 days. Antibiotics should be started in less than 24 hours after trauma.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ceftriaxone, azithromycin

Primary outcome measure
The frequency of bacterial meningitis in IV, O and P groups.

Secondary outcome measures
1. The frequency of rhinorrhoea, intracranial haemorrhage and skull base fracture, volume and location of intracranial air in the population study and each of the IV, O and P groups.
2. The mortality rate in study population and each of the IV, O and P groups

Overall study start date
01/12/2004

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Traumatic pneumocephalus verified by brain computed tomography (CT) scan
2. The patients should be hospitalised less than 24 hours after trauma

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
186

Key exclusion criteria
1. Patients who have received antibiotic therapy for other reasons
2. Individuals with penetrating traumatic brain injury, open skull fractures or operated for any causes
3. Those who are discharged from hospital with personal consent
4. All cases with life threatening lesions including severe brain, abdominal or vascular injuries and death due to other causes

Date of first enrolment
01/12/2004

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Iran

Study participating centre
Dept of Neurosurgery
Tehran
Iran
15116

Sponsor information

Organisation
Tehran University of Medical Sciences (TUMS) (Iran)

Sponsor details
Sina Trauma and Surgery Research Center
Sina Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01c4pz451

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sina Trauma and Surgery Research Center (Iran)

Funder Name
Tehran University of Medical Sciences (Iran)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/01/2006		Yes	No