

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Cephalexin and Azithromycin regimen for infection prophylaxis in simple dirty wounds treated at emergency department.

Protocol summary

Summary

It has been proven that limited use of antibiotics for infection prophylaxis in simple dirty wounds is quite useful and reasonable, especially when the wounds are closed primarily at emergency department. Cephalexin has been used for this purpose for decades. we are going to find another proper antibiotic regimen to replace it. Patients over 16 who are admitted to emergency department of Rasoul akram and Sina Hospital because of simple dirty wounds not obtaining any of exclusion criteria and their wound would undergone primary closure at emergency room will be randomly divided to two groups; one receiving 3 days regimen of Cephalexin (1gr before wound manipulation and 500mg QID for 3 days), and the other will get Azithromycin (500mg before wound manipulation and then 250mg daily). All patients will be visited after 48 hours of wound closure and at the time of sutures removal between 7 to 10 days, in addition to that all patients will be informed of infection signs and symptoms and would be asked to contact the researcher for observing the wound and treating the infection. by the end of study the incidence of infection in two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012071810017N3**
Registration date: **2012-07-24, 1391/05/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-24, 1391/05/03

Registrant information

Name

Hamed Basir Ghafouri

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences, Tehran, Iran.

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2012-08-05, 1391/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Cephalexin and Azithromycin regimen for infection prophylaxis in simple dirty wounds treated at emergency department.

Public title

effect of azithromycin on the prevention of wound infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: presence of traumatic simple wounds with indication of antibiotic prophylaxis according to responsible physician's opinion Exclusion criteria: presence of penetrating wound, longer than 12 hours, presence of diabetes, cirrhosis, or renal failure, current

using of antibiotics or immunosuppressive agents, splenectomy, prosthetics heart valves, immunosuppressive disorders, fractures at the site of wound, bites, joint, neurovascular or tendon involvement

Age

From **16 years** old to **149 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran Universty of Medical Sciences Ethics Committee

Street address

Keshavarz Blvd, Qods St. Headquarter for Tehran University of Medical Sciences,

City

Tehran

Postal code

Approval date

2012-03-29, 1391/01/10

Ethics committee reference number

130/2649/90/3

Health conditions studied

1

Description of health condition studied

traumatic wounds management

ICD-10 code

T79.3

ICD-10 code description

Post-traumatic wound infection, not elsewhere classified

Primary outcomes

1

Description

infection

Timepoint

48 hr,240 hr

Method of measurement

presence of either a stitch abscess, cellulitis greater than 1 cm,or purulent drainage

Secondary outcomes

empty

Intervention groups

1

Description

control:oral cephalixin 1000 mg befor wound manipulation and then 500 mg q 6 h for 3 days

Category

Treatment - Drugs

2

Description

intervention:oral azithromycin 500 mg befor manipulation and then 250 mg daily for 3 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Hamed Basir Ghafouri

Street address

Hasan abad sq., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhundzadeh

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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

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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