

# 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

Iran (Islamic Republic of)

##### Phone

+98 21 6653 9233

##### Email address

h-basirghafouri@tums.ac.ir

##### 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

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr Shahin Akhundzadeh

##### Street address

Keshavarz Blvd. Pour Sna street.Tehran University of Medical Siences, School of Medicine .first floor .No303

##### 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

**Name of organization / entity**  
Tehran University of Medical Sciences, School of Medicine  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Email**  
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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*