Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of effectiveness of oral antibiotic with intravenous antibiotic in prophylaxis of wound infection in patients with hand laceration who come to emergency department

Protocol summary

Summary

Aims: Evaluation of effectiveness of oral antibiotic with intravenous antibiotic in prevention of wound infection in patient with hand laceration. Inclusion and exclusion criteria:Inclusion Criteria consist of patients consent to participation in the study and patients with class 2 hand laceration , exclusion criteria consist of unwillingness to study participation and admission to hospital wards due to any risen. Study population: All patients with hand laceration who come to emergency wards of Shariati and Sina Hospital during the recruitment period. Sample size: According to analysis the total sample size in both groups are 746 patients. Intervention: In first group patients receive intravenous cefazolin per KG of body weight before procedure and then discharged home with oral cephalexin for 48 hours. In second group, patients receive oral cephalexin per KG of body weight before procedure and then discharged home with oral cephalexin for 48 hours.Triage nurse gives drugs to patients randomly according to study groups. patients, physicians and statistics specialist are blind to data and administered drugs in the whole of the study. In cefazolin group patients receive an oral placebo similar to cephalexin capsules and in oral cephalexin patients receive normal saline as a placebo. Primary outcomes: All patients evaluate after 48 hours for sign of wound infection such as erythema, swelling and secretion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707118872N12**
Registration date: **2017-07-23, 1396/05/01**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-23, 1396/05/01

Registrant information

Name

Morteza Saeedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2719

Email address

m_saeedi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research deputy of medicine faculty of Tehran University of Medical Sciences

Expected recruitment start date

2017-07-27, 1396/05/05

Expected recruitment end date

2018-01-25, 1396/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of oral antibiotic with intravenous antibiotic in prophylaxis of wound infection in patients with hand laceration who come to emergency department

Public title

oral antibiotic effectiveness in prevention of wound

infection in hand laceration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: patients consent to participation in the study; patients with class 2 hand laceration whom treated by emergency physicians. Exclusion Criteria: patients with crash laceration; hand laceration accompanied by tendon injury that mandate patient admission; open fractures; bite wound; patient needed to admission to other services; laceration which needed to repair in operating room; allergic history to cephalosporins.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **764**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Siences

Street address

floor 5, NO 226,Poursina avenue, Ghods avenue,Enghelab square, Tehran

City

Tehran

Postal code

Approval date

2016-10-04, 1395/07/13

Ethics committee reference number

IR.TUMS.REC.2845

Health conditions studied

1

Description of health condition studied

hand laceration

ICD-10 code

s61.9

ICD-10 code description

Open wound of wrist and hand part, part unspecified

Primary outcomes

1

Description

prevalence of wound infection

Timepoint

48 hours after wound repair

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group, patients receive oral cephalexin per KG of body weight before procedure and receive normal saline as a placebo then discharged home with oral cephalexin for 48 hours.

Category

Treatment - Drugs

2

Description

In control group patients receive intravenous cefazolin per KG of body weight before procedure and patients receive an oral placebo similar to cephalexin capsules then discharged home with oral cephalexin for 48 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Sina and Shariati Hospitals

Full name of responsible person

Morteza Saeedi

Street address

Sina Hospital (Hsanabad Square)and Shariati Hospital(beside Eghtesad university; Al Ahmad high way; North Kargar avenue) Emergency Departement

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences -Faculty of Medicine
Full name of responsible person
Shahin Akhondzadeh Basti
Street address
Building No 1, North entrance door of Tehran University, Poursina sreet, Qods street, Enghelab street
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 -Faculty of Medicine
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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Web page address

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