

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of infection rate for sterile vs unsterile but clean gloves in repairing of contaminated simple traumatic wounds in emergency department

Protocol summary

Summary

Use of clean nonsterile gloves versus sterile gloves in contaminated simple traumatic wounds repair in ED can reduce treatment costs significantly. For this purpose in this trial we will compare post operative infection rate in two randomized repaired contaminated simple wounds groups with sterile & nonsterile clean gloves in emergency department of 7th tir hospitals during 22/11/2010 to 22/7/2011. Our 200 desired cases include all simple traumatic contaminated wounds with indication of antibiotic prophylaxis & exclusion criteria and without age limitation. They will be selected in a convenience sampling and will be divided into two equal groups using table of random numbers. In one group we will suture the simple contaminated traumatic wounds with sterile gloves and in other group use clean nonsterile gloves. For both groups oral prophylactic antibiotic will be prescribed at the same regimen for 5 days. Within following ten days, patients will be asked through phone about the infection symptoms (redness, inflammation, warmth, pus discharge, fever). After reaching the desired number of cases we will analyze data with SPSS software to discerning if it meaningful differences in infection between two groups. All infected wounds will be followed at the hospital emergency clinic.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011175193N1**
Registration date: **2011-02-05, 1389/11/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-02-05, 1389/11/16

Registrant information

Name

Shafea jafar Zoofaghari

Name of organization / entity

Tehran University Of Medical Science & Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 5522 8573

Email address

hbgssl@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Science & Health Services

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of infection rate for sterile vs unsterile but clean gloves in repairing of contaminated simple traumatic wounds in emergency department

Public title

Outcome of clean unsterile gloves in post repaired wounds infection rate

Purpose

Treatment

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

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Science & Health Services

Street address

Crossroad of Hemmat & Fazl-allah Expway

City

Tehran

Postal code

Approval date

2010-10-10, 1389/07/18

Ethics committee reference number

7/895

Health conditions studied

1

Description of health condition studied

Traumatic simple and contaminated wounds of body

ICD-10 code

S00, T98

ICD-10 code description

Injury, poisoning and certain other consequences of external causes

Primary outcomes

1

Description

Infection rate

Timepoint

for 10 days after repair

Method of measurement

Asking about infection symptoms by phone (redness, inflammation, warmth, pus discharge, fever)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: use of clean unsterile gloves

Category

Treatment - Devices

2

Description

Control: use of sterile gloves

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

7th tir Hospital

Full name of responsible person

Dr. Shafea Jafar Zoofaghari

Street address

7th Hospital, Rajae St. Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University Of Medical Sciences & Health Services

Full name of responsible person

Research Committee

Street address

Crossroad of Hemmat & Fazl-allah Expway

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 & Health Services

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 Science & Health Services

Full name of responsible person

Shafea Jafar Zoofaghari

Position

Emergency Medicine Resident

Other areas of specialty/work**Street address**

Rasooleakram Hospital, Sttarkhan St.

City

Tehran

Postal code

8199934388

Phone

00983112302940-00982166525327

Fax**Email**

sh.zf9438@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University Of Medical Science & Health Services

Full name of responsible person

Hamed Basir Ghafoori

Position

Emergency Medicine Specialist

Other areas of specialty/work**Street address**

Rasooleakram Hospital

City

Tehran

Postal code**Phone**

+98 21 6652 5327

Fax**Email**

hbgssl@iums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University Of Medical Sciences & Health Services

Full name of responsible person

Shafea Jafar Zoofaghari

Position

Emergency Medicine Resident

Other areas of specialty/work**Street address**

Rasooleakram Hospital- Sattarkhan St.

City

Tehran

Postal code

8199934388

Phone

00983112302940-00982166525327

Fax**Email**

sh.zf9438@gmail.com

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