

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of wound irrigation with 1% Povidone Iodine solution and normal saline on wound infection rate of patients with simple traumatic wound; A randomized clinical trial

Protocol summary

Summary

Objectives: Prevention of wound infection is one of the most important tasks during wound management in emergency departments. **Design:** This is a non-blind, interventional, randomized clinical trial. **Setting:** This study will be conducted in 2 academic emergency department with 100000 overall annual census. **Participants:** All patients older than 18 years and simple traumatic wound would be approached. Those with comorbid disease such as diabetes, cirrhosis or renal failure, those on antibiotics, steroids, immunosuppressive drugs and immunodeficient patients, those with injuries to bone and joint and other organs will be excluded. **Interventions:** Then they will assign to intervention and control group. In intervention group wounds will be irrigated with 50 milliliter per centimeter (ml/cm) of 1% Povidone Iodine solution and in control group wounds will be irrigated with 50 ml/cm of normal saline solution. **Main outcome measures:** They will revisit for wound check and any sign of wound infection and skin irritation in 2nd, 5th and 10th days after wound repair for any sign of wound infection. A telephone follow up will be scheduled for one month later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501038104N11**
Registration date: **2015-01-25, 1393/11/05**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-01-25, 1393/11/05

Registrant information

Name

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Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-01-30, 1393/11/10

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of wound irrigation with 1% Povidone Iodine solution and normal saline on wound infection rate of patients with simple traumatic wound; A randomized clinical trial

Public title

Povidone Iodine and wound infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Simple Traumatic Wound; Age over 18

years old Exclusion Criteria: Human or Animal bite; Tendon, nerve or vessel involvement; More than 12 hours since trauma; Concomitant joint or bone injuries; Any other traumatic injury to other organs; Bullet or high energy shrapnel wounds; Those on Antibiotics, Immunosuppressive drugs or steroids before trauma; Cirrhosis, Chronic Renal failure, Diabetes; Acquired or congenital immune compromised patients; Prosthetic heart valve; Allergy to Iodine; Chronic substance or alcohol abuse

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **350**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran University of Medical Sciences' Ethics committee

Street address

Hemmat Highway, Cross with Sheikh Fazlollah Highway

City

Tehran

Postal code**Approval date**

2014-12-17, 1393/09/26

Ethics committee reference number

93/d/105/4547

Health conditions studied**1****Description of health condition studied**

Wound

ICD-10 code

XIX

ICD-10 code description

Injury, poisoning and certain other consequences of external causes

Primary outcomes**1****Description**

Wound infection

Timepoint

2, 5, 10 and 30 days after procedure

Method of measurement

Direct observation in days 2, 5 and 10 and telephone follow up 30 days after procedure

Secondary outcomes**1****Description**

wound dehiscence and skin irritation

Timepoint

2, 5, 10 and 30 days after procedure

Method of measurement

Direct observation in days 2, 5, 10 after procedure and telephone follow up in day 30

Intervention groups**1****Description**

Intervention: Irrigation of wound with 50 ml/cm of wound length with 1% Povidone Iodine solution

Category

Treatment - Drugs

2**Description**

Control Irrigation of wound with 50 ml/cm of wound length with normal saline solution

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasoul Akram Hospital

Full name of responsible person

Marzieh Fathi

Street address

Niyayesh St, Sattarkhan Ave

City

Tehran

2

Recruitment center

Name of recruitment center

7th of Tir Martyres Hospital

Full name of responsible person

Mina Zavareh

Street address

Shahid Radjaye Blvd.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences Vice Chancellor of Research

Full name of responsible person

Seyyed Ali Javad Mousavi

Street address

Hemmat Highway, Cross with Sheikh Fazlollah Hwy

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences Vice Chancellor of Research

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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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