

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of prophylactic antibiotic in prevention of surgical site infection in inguinal hernioplasty with mesh in patients referring Isfahan's Dr. Shariati Hospital

Protocol summary

Summary

Purpose: This study was designed to evaluate the effect of prophylactic antibiotic in prevention of surgical site infection after hernioplasty with mesh. We will include all male patients who are candidates for elective hernioplasty with mesh and we will exclude patients with indications for emergency surgery such as recurrent or strangulated hernia; positive history of immunosuppressive disease; allergy to the given antibiotic; history of antibiotic usage 3 days before surgery. Material and methods: this study is a double-blind randomized clinical trial. Our estimated sample size of 100 participants. Patients who has the inclusion criteria undergo elective hernioplasty with polypropylene mesh. 30 to 45 minutes before surgery, patients were randomly take 1 gr intravenous cefazolin or the same volume of sterile saline. Patients will be evaluated 1 week, 6-8 week after surgery (according to the Center for Disease Control).The third follow up will be conducted by telephone 12 weeks after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090210719N1**

Registration date: **2012-11-28, 1391/09/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-28, 1391/09/08

Registrant information

Name

shahriar barkhordary

Name of organization / entity

islamic azad university, najafabad branch

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Islamic Azad university, Najafabad Branch

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of prophylactic antibiotic in prevention of surgical site infection in inguinal hernioplasty with mesh in patients referring Isfahan's Dr. Shariati Hospital

Public title

The effect of antibiotic prophylaxis in the prevention of surgical site infection after hernia surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all male patients with Primary Inguinal Hernia who are candidates for elective hernioplasty with mesh. Exclusion criteria: patients younger than 18 years old; patients with a recurrent, strangulated, giant scrotal

or femoral hernia; patients who are indicated for emergency hernia surgery; patients with a history of diabetes mellitus; patients with underlying heart, liver, renal disease, AIDS or malignancy; patients with American Society of Anesthesiologists (ASA) scores more than II; patients treated with glucocorticoid; patients with allergy to the given antibiotic; patients taking some antibiotic 3 days prior to surgery; Use of drain; refusing to participate in the study.

Age

From **18 years** old to **149 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezarjarib Ave

City

Isfahan

Postal code

Approval date

2012-09-09, 1391/06/19

Ethics committee reference number

491003

Health conditions studied

1

Description of health condition studied

inguinal hernia

ICD-10 code

K40.9

ICD-10 code description

Unilateral or unspecified inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description

surgical site infection

Timepoint

1, 6-8 and 12 weeks after operation

Method of measurement

Clinical exam, culture and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

10 cc intravenous sterile saline 30-45 min before surgery
in control group

Category

Placebo

2

Description

1 gr intravenous cefazolin 30-45 minutes before surgery
in case groupe

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan's Dr. Shariati Hospital

Full name of responsible person

Dr. Behnam Yazdani

Street address

Dr. Shariati Hospital, Shariati Ave

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Najafabad Branch

Full name of responsible person

Dr. Reza Ebrahimi

Street address

Daneshgah Blvd

City

Najafabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University, Najafabad Branch

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

Islamic Azad University, Najafabad Branch

Full name of responsible person

Shahriar Barkhordary

Position

Intern

Other areas of specialty/work

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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