Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Intern

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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