

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of prophylactic antibiotic effectiveness in prevention of wound infection in Lichtenstein inguinal hernioplasty with mesh in patients referring Sari,s ImamKhomeini and Qaemshahr,s Razi hospitals

Protocol summary

Summary

“Evaluation of prophylactic antibiotic effectiveness in prevention of wound infection in Lichtenstein inguinal hernioplasty with mesh” Background and purpose: Inguinal hernioplasty is one of the most surgical operations. The use of prophylactic antibiotic in Lichtenstein hernioplasty is controversial. Hence this study done to evaluate the prophylactic antibiotic effect in reducing the post operative wound infection in Lichtenstein hernioplasty. Material and Methods: This is an interventional double-blind randomized trial on 282 patients under going, Unilateral primary elective inguinal hernioplasty with Lichtenstein method. Using polypropylene mesh. They were randomized to receive 1gr/1v cephalotin (keflin) or equal volume of placebo 30min before incision. Patients were evaluated 1week, 2weeks and 12weeks after surgery by an independent surgeon or resident. Wound infection was defined according to the criteria of centers for Disease control and recorded. Results were assessed using chi-square and t-test as appropriate. Inclusion criterion: any patient suffering from inguinal hernia undergone elective lichtenstein hernioplasty Exclusion criteria: 1.urgent hernia repair due to incarceration or strangulation 2.recurrent hernia 3.allergy to keflin or penicillins 4.need to use antibiotics due to other preoperation reasons; for example: valvular heart disease or infectious diseases 5.immunosuppression 6.the patient refuses to participate in clinical trial

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203121786N4**

Registration date: **2012-06-10, 1391/03/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-10, 1391/03/21

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2010-06-10, 1389/03/20

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of prophylactic antibiotic effectiveness in prevention of wound infection in Lichtenstein inguinal hernioplasty with mesh in patients referring Sari,s ImamKhomeini and Qaemshahr,s Razi hospitals

Public title

Evaluation of prophylactic antibiotic effectiveness in prevention of wound infection in lichtenstein hernioplasty with mesh.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criterion: any patient suffering from inguinal hernia undergone elective lichtenstein hernioplasty

Exclusion criteria: 1.urgent hernia repair due to incarceration or strangulation 2.recurrent hernia 3.allergy to keflin or penicillins 4.need to use antibiotics due to other preoperation reasons; for example: valvular heart disease or infectious diseases 5.immunosuppression 6.the patient refuses to participate in clinical trial

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 282

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

Mazandaran University of Medical Sciences

Street address

Sari- Imam SQ

City

Sari

Postal code

Approval date

2010-06-09, 1389/03/19

Ethics committee reference number

8933

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

Wound infection

Timepoint

One, 2 and 12 weeks postoperation

Method of measurement

Clinical exam and culture

Secondary outcomes

empty

Intervention groups

1

Description

in casegroup 1gr keflin 30 min before surgery

Category

Prevention

2

Description

and in control group distilled water 30min before surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Imam Khomeini hospital

Full name of responsible person

Mohammad Kermansaravi- MD

Street address

Sari- Imam Khomeini hospital

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ahmadali Enayati

Street address

Sari- Mazandaran University of Medical Sciences

City

Sari

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran University of Medical Sciences

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**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Mohammad Kermansaravi

Position

MD

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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