

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of surgical site infection in Mesh Hernioplasty in with or without glove change

Protocol summary

Wound infection after inguinal hernia surgery with mesh

Study aim

Evaluation of surgical site infection in Mesh Hernioplasty with or without glove change

Design

A concealed, blinded, sham-controlled clinical trial with parallel groups. Patients are randomly divided into two groups. The risk of infection in the placement of the mesh by changing gloves and without changing in the inguinal hernia is assessed. Patients are matched in terms of sex and type of hernia. Indeed six lines are created for random allocation, and the entered individuals in each line are assigned to group A or B by a simple randomization method. The assignor does not have contact with subsequent evaluators. Patients are randomly divided into 2 groups of 100, using codes A and B that patients choose before surgery. Preoperative prophylaxis is done but no antibiotics are given after the surgery. All patients are thoroughly examined in the outpatient clinic on the day of discharge from the hospital (second day after surgery) and 10 and 30 days after surgery.

Settings and conduct

In this double-blind study, the nurse and evaluator are unaware of grouping. This study will be performed in Imam Reza Hospital of Mashhad. Patients referred to the surgical ward of Imam Reza Hospital will be selected. These patients will be all candidates for inguinal hernia surgery with mesh.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Conscious satisfaction, candidate for inguinal hernia surgery with mesh, no underlying diseases such as diabetes. Exclusion criteria: dissatisfaction with inclusion in the study, having an underlying disease such as diabetes.

Intervention groups

Intervention group: Changing gloves during the operation. Control group: No gloves replacement during the operation

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090124001581N4**

Registration date: **2021-05-18, 1400/02/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-18, 1400/02/28**

Update count: **0**

Registration date

2021-05-18, 1400/02/28

Registrant information

Name

Mohammad Reza Motie

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5255

Email address

motiem@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2022-11-06, 1401/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of surgical site infection in Mesh Hernioplasty in with or without glove change

Public title

Evaluation of surgical site infection in Hernioplasty in with or without glove change

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious satisfaction, candidate for inguinal hernia surgery with mesh, no underlying diseases such as diabetes

Exclusion criteria:

dissatisfaction with inclusion in the study, having an underlying disease such as diabetes

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, health care providers (nurses) and outcome assessors are not aware of the two study groups. The surgeon knows the groups of patients. Therefore, the evaluator is someone other than the surgeon. Also, after the operation, the nurse does not know about the study groups, and there is no difference in the way of care between the two groups of patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical

Sciences

Street address

Danehgah street, Ethics committee of Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Approval date

2020-12-09, 1399/09/19

Ethics committee reference number

IR.MUMS.REC.1399.513

Health conditions studied

1

Description of health condition studied

Inguinal hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

Wound infection

Timepoint

On the second, third and thirty days after surgery

Method of measurement

Physical examination and tissue culture

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, glove replacement will be performed during inguinal hernia surgery

Category

Prevention

2

Description

Control group: in the control group, glove replacement is not performed in the inguinal hernia

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Mashhad

Full name of responsible person

Mohammadreza Motie

Street address

Malekoshoara Bahar street, Imam Reza Hospital of Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Daneshgah St., Alouk University of Medical Sciences, Mashhad, second floor, Vice Chancellor

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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

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohammadreza motie

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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Position

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Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all collected deidentified IPD are to be shared

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

available for people working in academic institutions

Under which criteria data/document could be used

With the coordination of the corresponding author is determined.

From where data/document is obtainable

Via corresponding author email

What processes are involved for a request to access data/document

Applicants can access the data by emailing the responsible author and a full description of the processes that will be performed on the data.

Comments