

# 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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1394491388

**Phone**

+98 51 3841 2081

**Email**

Motiem@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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**Phone**

+98 51 3845 1521

**Email**

tafaghodim@mums.ac.ir

**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

**Street address**

Imam Reza Hospital of Mashhad

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

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**Phone**

00985138412081 051

**Email**

motiem@mums.ac.ir

## Person responsible for scientific 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

**Street address**

Imam Reza Hospital of Mashhad

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**Phone**

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**Email**

motiem@mums.ac.ir

## Person responsible for updating data

#### 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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**Province**

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**Postal code**

1394491388

**Phone**

+98 51 3841 2081

**Email**

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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**