# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Investigating the effect of subcutaneous area repair or non-repair on the incidence of complications of Inguinal hernia surgery.

## Protocol summary

**Study aim**

Comparison of two methods for repairing or not repairing the subcutaneous region in the incidence of complications of inguinal hernia surgery wounds

**Design**

92 patients referred to Amiralmounin Hospital in Arak, who are diagnosed with inhumane hernia surgery, are included in this study. They are randomly assigned to two groups using a random number table. The intervention group undergoing surgery with subcutaneous suture and the control group whose surgery will be subcutaneously sutured. This double-blind, double blinded study is the first blinded patient who is unaware of being in the intervention group. The second blinded person is responsible for the evaluation of postoperative complications that are unknown. The patient is being examined in which intervention and control group. Patients are examined for complications on the first, third, seventh and tenth day.

**Settings and conduct**

Patients require ingenial hernia surgery in Amiralmounin Hospital in Arak, Iran. They are randomly divided into two groups. The intervention group undergoing surgery with subcutaneous suture and the control group whose surgery will be subcutaneously sutured. Patients are examined for complications on the first, third, seventh and tenth day.

**Participants/Inclusion and exclusion criteria**

Entry requirements: ages 20 to 50 years, having more than 3 cm holes in the groin area Conditions of non entering: Diabetes, cancer, having stomach ulcers in the groin area of the groin

**Intervention groups**

Intervention group: Patients undergoing hernia surgery on the thighs do not undergo subcutaneous suturing after surgery and during suturing of the skin. Control group: Patients undergoing thoracic hernia surgery undergo subcutaneous sutures after surgery and during suturing of the skin.

**Main outcome variables**

Inflammation, infection, seroma, hematoma and wound closure in the surgery area.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20161017030336N3**
Registration date: **2018-12-07, 1397/09/16**
Registration timing: **retrospective**

Last update: **2018-12-16, 1397/09/25**
Update count: **1**

**Registration date**

2018-12-07, 1397/09/16

**Registrant information**

**Name**
Ghasem Habibi

**Name of organization / entity**
Islamic azad university

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2017-12-01, 1396/09/10

**Expected recruitment end date**

2018-03-11, 1396/12/20

**Actual recruitment start date**

2018-03-11, 1396/12/20

**Actual recruitment end date**
2018-03-11, 1396/12/20
**Trial completion date**
2018-03-11, 1396/12/20

**Scientific title**
Investigating the effect of subcutaneous area repair or non-repair on the incidence of complications of Inguinal hernia surgery.

**Public title**
Investigating the effect of subcutaneous area repair or non-repair on the incidence of complications of Inguinal hernia surgery.
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age between 20 and 50 years Having more than 3 cm ulcers in the inguinal hernia.
**Exclusion criteria:**
Having a Diabetes Mellitus. The patient has cancer. Having scars in the inguinal hernia area.
**Age**
From **20 years** old to **50 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **92**
Actual sample size reached: **92**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Control and intervention groups will be selected randomly using random number table
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Not being aware of the presence of the participants in the intervention and control group. The lack of knowledge of the researcher from the participants in the intervention and control group.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Arak University of Medical Sciences
**Street address**
Basidj Bridge, Sadasht.
**City**
Arak
**Province**
Markazi
**Postal code**
3819693345
**Approval date**
2017-11-26, 1396/09/05
**Ethics committee reference number**
IR.ARAKMU.REC.1396.183

## Health conditions studied

**1**

**Description of health condition studied**
Inguinal hernia
**ICD-10 code**
K40.9
**ICD-10 code description**
Unilateral inguinal hernia, without obstruction or gangrene

**2**

**Description of health condition studied**
Complications of surgical wound
**ICD-10 code**
T81
**ICD-10 code description**
Complications of procedures, not elsewhere classified

**3**

**Description of health condition studied**
Complications of surgical wound
**ICD-10 code**
T81.4
**ICD-10 code description**
Infection following a procedure

## Primary outcomes

**1**

**Description**
Inflammation in the wound of the surgery
**Timepoint**
1,3,5,7,10 days after surgery
**Method of measurement**
Inflammation is a physiological response to various stimuli, such as infections and tissue wounds, which quickly develop and end. It can be viewed visually.

**2**

**Description**
The presence of serum in the surgical wound area
**Timepoint**
1,3,5,7,10 days after surgery
**Method of measurement**
The accumulation of non-empty fluid in the surgeon is called serum. And visually visible.

**3**

**Description**
Infection in the surgical wound area
**Timepoint**
1,3,5,7,10 days after surgery
**Method of measurement**
The accumulation of purulent fluid in the surgical area of infection is called. And visually visible.

**4**

**Description**
Opening of surgical wound
**Timepoint**
1,3,5,7,10 days after surgery
**Method of measurement**
Visually visible.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Patients undergoing hernia surgery on the thighs do not undergo subcutaneous suturing after surgery and during suturing of the skin
**Category**
Treatment - Surgery

**2**

**Description**
Control group: Patients undergoing thoracic hernia surgery undergo subcutaneous sutures after surgery and during suturing of the skin
**Category**
Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Amir Al-Momenin Hospital
**Full name of responsible person**
Dr.Mahdi Mohammadjavadi
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## Sponsors / Funding sources

**1**

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**Grant name**
**Grant code / Reference number**
2940
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Arak 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**
Arak University of Medical Sciences

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Dr. Amir Reza Na'imi

**Position**
Assistant Professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
General Surgery

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resident

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Research Assistant

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Bachelor

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Traditional Medicine

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Not applicable

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Not applicable

**Data Dictionary**
Not applicable