

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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 inguinal 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 inguinal 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

Country

Iran (Islamic Republic of)

Phone

+98 86 3367 3208

Email address

dr.habibi@arakmu.ac.ir

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.

AgeFrom **20 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget 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

Street address

Pardis of Arak University of Medical Sciences,
Sardasht, Basidj Bidge, Arak, IR. IRAN

City

arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Fax

+98 86 3417 3505

Email

danesh_m90@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Research Assistant of Arak University of Medical
Sciences:Dr. Mohammad Arjomandzadegan

Street address

Pardis of Arak University of Medical Sciences,
Sardasht, Basidj Bidge, Arak, IR. IRAN

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Fax

+98 86 3417 3505

Email

mmatinam81@yahoo.com

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

Full name of responsible person

Dr. Amir Reza Na'imi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Pardis of Arak University of Medical Sciences,
Sardasht, Basidj Bidge, Arak, IR. IRAN

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Fax

+98 86 3417 3505

Email

amirrezanaimi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mahdi Mohammadjavadi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Pardis of Arak University of Medical Sciences,
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City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Fax

+98 86 3417 3505

Email

danesh_m90@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ghasem Habibi

Position

Research Assistant

Latest degree

Bachelor

Other areas of specialty/work

Traditional Medicine

Street address

Pardis of Arak University of Medical Sciences,
Sardasht, Basidj Bidge, Arak, IR. IRAN

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Fax

+98 86 3417 3505

Email

ghasemhabibi.chem@gmail.com

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