

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Technical comparison of intercostal flank and subcostal flank incisions in open kidney surgeries

Protocol summary

Study aim

Technical comparison of subcostal and intercostal flank skin incisions in open kidney surgeries

Design

This clinical trial will be conducted on 64 patients who are candidates for open kidney surgery with the mentioned entry and exit criteria. The studied samples will be selected as available and randomly divided into intervention groups. The samples are divided into two equal groups of intercostal flank incision (32 samples) and subcostal flank incision (32 samples) using the block randomization method.

Settings and conduct

The present study is a randomized and blinded clinical trial study that will be conducted on 64 patients undergoing open kidney surgery in the operating room of Shahid Beheshti Hospital and Bou Ali Sinai Hospital in Hamedan. The participants are randomly divided into two equal groups and the intervention will be performed on them and its consequences will be evaluated in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Patients who are candidates for open kidney surgery • Age between 18 and 55 years • BMI between 18 and 30 Exit criteria: • Longer incision 30 cm • Re-operation with a cut on the previous incision • Presence of abdominal wall hernia at the same time • Diabetic participant • Being pregnant if the person participating in the study is a woman • History of peritoneal dialysis, previous hernia, taking immunosuppressive drugs, smoking and drug use, connective tissue diseases and disorders • Having a surgical site infection after surgery • Presence of ascites and abdominal distension after surgery

Intervention groups

1. Subcostal Flank incision 2. Intercostal Flank incision

Main outcome variables

Hernia and bulge after surgery; Pain after surgery; The amount of painkillers received; Postoperative scar;

Incision time; Time to suture the incision; Exposure of the operation field ; Quality of Life after surgery;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230208057358N1**

Registration date: **2023-02-11, 1401/11/22**

Registration timing: **prospective**

Last update: **2023-02-11, 1401/11/22**

Update count: **0**

Registration date

2023-02-11, 1401/11/22

Registrant information

Name

alireza abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3426 3597

Email address

al.abdi@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-28, 1401/12/09

Expected recruitment end date

2023-08-31, 1402/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Technical comparison of intercostal flank and subcostal flank incisions in open kidney surgeries

Public title

Technical comparison of intercostal flank and subcostal flank incisions in open kidney surgeries

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients are candidates for open kidney surgery
Willingness and consent to participate in the study
Body mass index (BMI) between 18 and 30

Exclusion criteria:

Re-operation with a cut on the previous incision
Presence of abdominal wall hernia at the same time
The person participating in the study is diabetic
Being pregnant if the person participating in the study is a woman
History of chronic obstructive pulmonary disease
History of peritoneal dialysis
History of previous hernia
History of taking immunosuppressive drugs
History of smoking and drug use
History of connective tissue diseases and disorders

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The studied samples will be selected as available and randomly divided into intervention groups. The samples are divided into two equal groups of intercostal flank incision (A) and subcostal flank incision (B) using the block randomization method. Our randomization tool in this study is random allocation software version 1, which is available at

<https://mahmoodsaghaei.tripod.com/Softwares/randalloc.html>. The information required by the software, including the number of groups (2 groups), the name of each group (A=1, B=2), sample size (64 patients) and block size (4) were entered to generate a random sequence and based on that, 16 blocks of 4 including two groups A and B were randomly designed using the software. In this study, we will use the concealment of random allocation for the purpose of concealment, which refers to the method used to perform a random sequence on the participants in the study, in such a way that the allocated group is not known before the allocation of the individual. In this method, each of the generated random sequences is recorded on a card and the cards will be

placed in sealed opaque envelopes in order. In order to maintain a random sequence on the outer surface of the envelopes, numbering will be done in the same order. Finally, the lid of the letter envelopes will be glued and placed in a box. At the time of registration of participants, based on the order of entry of qualified participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will not know which surgical incision technique was used for them.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for research and technology, In front of the Mardom park, Shahid Fahmideh steet, Hamadan

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2023-01-27, 1401/11/07

Ethics committee reference number

IR.UMSHA.REC.1401.937

Health conditions studied**1****Description of health condition studied**

open kidney surgeries; flank hernia and bulge

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Hernia and bulge after surgery

Timepoint

At times 3 and 6 months after the operation

Method of measurement

Clinical examination by a specialist surgeon and medical imaging

2

Description

Pain after surgery

Timepoint

in 1 and 3 months after surgery

Method of measurement

Visual analog scale (VAS)

3

Description

The amount of painkillers received

Timepoint

At the time of discharge from the hospital

Method of measurement

Injection syringe (in milliliters)

4

Description

Surgical incision scar

Timepoint

At times 3 and 6 months after the operation

Method of measurement

Manchester scar scale

5

Description

Incision time

Timepoint

During surgery

Method of measurement

Digital clock (in minutes)

6

Description

Closure time

Timepoint

During surgery

Method of measurement

Digital clock (in minutes)

7

Description

Exposure of the operative site

Timepoint

Immediately after surgery

Method of measurement

Likert scale - scoring from one (suitable and sufficient exposure - highest satisfaction) to five (inappropriate and poor exposure - lowest satisfaction) -

8

Description

Quality of Life

Timepoint

Once before surgery and 1 and 3 months after surgery

Method of measurement

SF-36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Flank intercostal cut (lateral oblique cut between the 11th and 12th ribs from the rectus sheath to the sacrospinalis muscle)

Category

Treatment - Surgery

2

Description

Control group: Subcostal flank incision (diagonal flank incision that is made about 2 cm below the 12th rib from the rectus sheath to the Sacrospinalis muscle)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Dr Behzad Imani

Street address

At the beginning of Eram Boulevard, Hamadan

City

Hamadan

Province

Hamadan

Postal code

65179-5-3371

Phone

+98 81 3838 0706

Email

shahidbeheshti@umsha.ac.ir

Web page address

<http://beheshti.umsha.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Behzad Imani

Street address

Hamedan University of Medical Sciences, Shahid
Fahmideh St., Pazhouhesh Square, Hamadan

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone

+98 81 3131 0000

Email

Webda@umsha.ac.ir

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

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Alireza Abdi

Position

MSc student in Surgical technology

Latest degree

Bachelor

Other areas of specialty/work

Others

Street address

No 110, Imam Khomeini St., Maryanaj

City

hamadan

Province

Hamadan

Postal code

6514144868

Phone

+98 81 3426 3597

Email

al.abdi@edu.umsha.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Alireza Abdi

Position

MSc student in Surgical technology

Latest degree

Bachelor

Other areas of specialty/work

Others

Street address

No 110, Imam Khomeini St., Maryanaj

City

hamadan

Province

Hamadan

Postal code

6514144868

Phone

+98 81 3426 3597

Email

al.abdi@edu.umsha.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Alireza Abdi

Position

MSc student in Surgical technology

Latest degree

Bachelor

Other areas of specialty/work

Others

Street address

No 110, Imam Khomeini St., Maryanaj

City

Hamadan

Province

Hamadan

Postal code

6514144868

Phone

+98 81 3426 3597

Email

al.abdi@edu.umsha.ac.ir

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

Yes - There is 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

Undecided - It is not yet known if there will be a plan to

make this available

Informed Consent Form

Yes - There is 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

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

Data Dictionary

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

Title and more details about the data/document

In this study, it will find part of the same data as the information related to the main outcome, follow-ups, and background and demographic information of the participants with the aim of researching the publication.

When the data will become available and for how long

No decision has been made yet

To whom data/document is available

The results of this study will be available for researchers working in academic and scientific institutions, surgeons, residents and nurses working in the clinical field.

Under which criteria data/document could be used

No decision has been made yet

From where data/document is obtainable

To receive documents or get guidance, people can access the email of the person responsible for this study at the address below. Email address:
al.abdi@edu.umsha.ac.ir

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

No decision has been made yet

Comments