Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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
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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
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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