Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Technical comparison of two Lower midline and Pfannenstiel skin incisions in open prostatectomy: randomized clinical trial

Protocol summary

Study aim
Technical comparison of Lower midline and Pfannenstiel skin incisions in open prostatectomy surgery

Design
It is a randomized, double-blind, parallel-group clinical trial. In which 62 patients will be divided into two Pfannenstiel and lower midline groups by randomization method of four random blocks.

Settings and conduct
Data will be collected from Shahid Beheshti Hospital in Hamedan. The researcher will collect the required data by being present in the operating room of the mentioned hospital. In order to blind the participants, general explanations about the study will be given when obtaining the consent form, and the participants will not be aware of the type of surgery.

Participants/Inclusion and exclusion criteria
Entry requirements: Ability to communicate effectively with the researcher -Not having an underlying disease disrupting the research results, such as immune system diseases or coagulation disorders-Not having psychological diseases- Not taking immunosuppressive drugs Exit conditions: Failure to sign informed consent-Unwillingness to participate in the study-taking opioids

Intervention groups
In this study, the patients are randomly placed in two groups, Pfannenstiel and Lower Midline, and the aforementioned incisions are used for open prostatectomy surgery, and after that, the desired variables in groups are measured and compared.

Main outcome variables
Operation time-incision time-enucleation time-reach to the bladder time، Postoperative pain and postoperative painkillers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220822055769N1**
Registration date: **2022-08-31, 1401/06/09**
Registration timing: **prospective**

Last update: **2022-08-31, 1401/06/09**
Update count: **0**

Registration date
2022-08-31, 1401/06/09

Registrant information

Name
mojtaba moradzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Technical comparison of two Lower midline and Pfannenstiel skin incisions in open prostatectomy: randomized clinical trial

Public title
Comparison of two Lower midline and Pfannenstiel skin incisions in open prostatectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Ability to communicate with the researcher Absence of an underlying disease disrupting the research results, such as immune system diseases or coagulation disorders Not taking immunosuppressive drugs Absence of psychological diseases
Exclusion criteria:
Unwillingness to participate in the study Failure to sign informed consent Taking opioid drugs or substances
Age
No age limit
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize the patients, we will use the block randomization method of four. For this purpose, we prepare four sheets of paper. On two sheets we write the letter P meaning "Pfannenstiel" and on the other two sheets we write the letter L meaning "Lower midline". We mix the sheets together and put them in the desk drawer. With the referral of each of the qualified patients, one of the sheets will be randomly drawn and based on this drawn sheet, L or P, they will be assigned to one of the two treatment groups. It should be noted that the drawn cards will not be returned to the drawer until all four cards have been drawn. After randomly pulling out all four sheets, all the sheets are returned to the drawer and the above procedure will be continued for the next four patients until the desired sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to blind the data analyst, all the data obtained from the study will be given to the analyst without specifying the type of cut. In order to blind the participants, general explanations about the study will be given when obtaining the consent letter, and the participants will not be aware of their cut type.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamedan University of Medical Sciences
Street address
Ethics Committee in Research, Research and Technology Committee, University of Medical Sciences, Fahmideh Blvd
City
Hamedan
Province
Hamadan
Postal code
08138380130
Approval date
2022-08-20, 1401/05/29
Ethics committee reference number
IR.UMSHA.REC.1401.463

Health conditions studied

1

Description of health condition studied
Benign prostatic hyperplasia
ICD-10 code
N40
ICD-10 code description
Enlarged prostate

Primary outcomes

1

Description
Time of surgery
Timepoint
During surgery
Method of measurement
By using an electronic timer, the operation time is measured so that when the skin incision is started, the surgeon gives the order (start) and the researcher starts measuring the time, and after the last skin suture is applied and the last adhesive dressing is applied, The orders (time 1) and (time 2) will be issued by the surgeon. In this way, two different times for surgery will be measured.

2

Description
Time of incision
Timepoint
During surgery

Method of measurement
By using an electronic timer, the incision time is measured so that when the skin incision starts, the surgeon gives the order (start) and the researcher starts measuring the time, and when the rectus sheath incision starts, the surgeon will give the order (end). In this way, the incision time will be measured.

3

Description
Time of enucleation
Timepoint
During surgery
Method of measurement
Using an electronic timer, the enucleation time is measured so that when the surgeon's hand enters the bladder for enucleation, the surgeon gives the order (start) and the researcher starts measuring the time, and when all the desired parts of the prostate come out. The surgeon will give the order (end). In this way, the enucleation time will be measured.

4

Description
After surgery pain
Timepoint
Immediately after surgery, 12 hours after surgery and 24 hours after surgery
Method of measurement
Visual analogue scale will be used to evaluate postoperative pain. The scale consists of a 10 cm line with descriptive words at both ends. In most pain studies, the range is written from "no pain" to "severe pain" or "worst pain ever." In the current study, the phrases "no pain" to "the worst pain ever" will be used on both sides of the mentioned line. Patients estimate their pain level by placing a mark on the line. Then the distance from the "no pain" point is measured with a ruler. In order to validate the data obtained, a single ruler will be used throughout the data collection.

5

Description
After surgery scar
Timepoint
One month after surgery
Method of measurement
The Manchester scar scale will be used to evaluate the scar after the operation, which includes six items: color, appearance, texture, scar curvature, shiny surface, and the patient's general opinion. Each of the first four items is given a score between 1 and 4. Matt or shiny scar is recorded (score 1 and 2, respectively), and the patient's general opinion is measured on a 0-10 visual analogue scale. On one side of the line, the phrase (excellent) will be recorded and on the other side, the phrase (poor) will be recorded. The total marks are obtained from 6 items. Higher values indicate worse scars. Therefore, to measure the general opinion of the patient, the distance of the point recorded by the patient to the end (excellent) will be measured.

6

Description
The amount of painkillers received
Timepoint
During hospital stay
Method of measurement
The amount of painkiller received will be calculated in milliliters and an injection syringe manufactured by a single company will be used for measurement.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group P: Use of Pfannenstiel incision for simple open prostatectomy patients surgery-In this group, the Pfannenstiel skin incision, which is a lower transverse abdominal incision, is used for eligible patients presenting for open prostatectomy. Cutting is done using a scalpel blade. In the next steps, electrocautery, gauze, and Lon gauze are used for blood sampling.
Category
Treatment - Surgery

2

Description
Intervention group L: Use of lower midline incision for simple open prostatectomy patients surgery- In this group, the lower midline skin incision, which is a lower vertical abdominal incision, is used for eligible patients presenting for open prostatectomy. Cutting is done using a scalpel blade. In the next steps, electrocautery, gauze, and Lon gauze are used for blood sampling.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti medical educational center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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6517838736
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Email
Info.research@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
Mojtaba Moradzadeh
Position
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Latest degree
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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 personal data is shared after de-identifying individuals. including demographic data and data related to operation time, incision time, time to reach the bladder, enucleation time, postoperative pain level, painkiller received, and postoperative scar
When the data will become available and for how long
The data will be shared three months after the results are published.
To whom data/document is available
All researchers can take action to receive data.
Under which criteria data/document could be used
The data is provided under the condition that they first have a clear purpose for using the data. Second, wherever these data are to be used, the primary source of the data should be mentioned.
From where data/document is obtainable
To receive data, you can refer to the email address below. Behzadiman@yahoo.com
What processes are involved for a request to access data/document
After sending the request to the email address, the data will be sent as soon as possible.
Comments