Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Open Prostatectomy Patients In terms of Bleeding and Operative site Infection,with and without Surgicel

Protocol summary

Study aim
Control of bleeding and Infection in patients undergoing open prostatectomy with the use of surgical

Design
Clinical trial with intervention groups, with parallel groups, double-blinded, randomized

Settings and conduct
This study is carried out at Imam Reza Hospital in Tabriz. In this double-blind randomized clinical trial, 30 patients undergoing open prostatectomy.The patients will be randomized in one of the two groups with or without the use of surgical. During surgery, the amount of bleeding until the end of surgery in the two groups, will be investigated. All patients will be evaluated for hemoglobin, hematocrit and complications after transfer to the ward.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patient who are candidates for open prostatectomy، Patients aged 40 to 90 years، Having informed consent to participate in the study Non-inclusion criteria:Existence of an bleeding disorder, History of previous prostatic or urethral surgery, Having bladder stone.

Intervention groups
Intervention group: open prostatectomy with the use of surgical Control group: open prostatectomy without the use of surgical

Main outcome variables
Blood Loos, Infection, Inflammation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200219046557N1**
Registration date: **2020-03-26, 1399/01/07**
Registration timing: **registered_while_recruiting**
Last update: **2020-03-26, 1399/01/07**
Update count: **0**

Registration date
2020-03-26, 1399/01/07

Registrant information

Name
Hamed dadashkarimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3655 8304

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dadashkarimihamed@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Open Prostatectomy Patients In terms of Bleeding and Operative site Infection,with and without Surgicel

Public title
Evaluation of the effects of surgicel in open prostatectomy surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient who are candidates for open prostatectomy Patients aged 40 to 90 years Having informed consent to participate in the study
Exclusion criteria:
Existence of an bleeding disorder History of previous prostatic or urethral surgery; (c) Having bladder stone.

Age
From **40 years** old to **90 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Random method: Block, Random unit: individual, Random Tool: Random Block 4. for this purpose, 25 blocks with 4 subjects in each block will be used. the combination of all patterns will be considered including AABB, ABAB, BABA, BBAA, BABA, BAAB. For selecting each blocks, dice drooped and the block number will be selected. this procedure continued to completed the allocation and reached to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blinded study and Researcher and patients are kept unaware of intervention in each group and In order to allocation concealment, the type of intervention will be written on paper and placed in numbered, matte and packed envelopes.The envelopes will be opened in the order of participation of the participants and the type of group will be determined.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Science , Gholghasht street , Azadi street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Approval date
2020-02-17, 1398/11/28

Ethics committee reference number
IR.TBZMED.REC.1398.1215

Health conditions studied

1

Description of health condition studied
Open prostatectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Hemoglobin level

Timepoint
Preoperative, postoperative, days 2 and 3

Method of measurement
According to the lab and on the basis grams per deciliter

2

Description
Intraoperative blood loss

Timepoint
At the end of surgery

Method of measurement
The volume of blood absorbed by surgical gauze was estimated using Gauze Visual Analogue method. The mentioned figures plus the amount of blood in the surgical suction pump was considered as the total amount of intraoperative blood loss

3

Description
Hematocrit

Timepoint
Preoperative, postoperative, days 2 and 3

Method of measurement
According to the lab and on the basis percent

Secondary outcomes

1

Description
Infection

Timepoint
7 days after surgery

Method of measurement

Redness,secretion, tenderness in the wound or wound dehiscence

Intervention groups

1

Description
Intervention group: Surgicel (a topical cellulose homeostatic agent) will be used to control bleeding
Category
Treatment - Surgery

2

Description
Control group:Bleeding is controlled by an electrocautery (without the use of surgical)
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Sciences, Imam Reza Hospital
Full name of responsible person
Hamed Dadashkarimi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Web page address
https://www.tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Hamed Dadashkarimi
Position
Resident of Urology
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Full name of responsible person
Mohsen Amjadi

Position
Associate professor/ Urologist
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Other areas of specialty/work
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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
No - There is not 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
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
A portion of the data that represents the final outcome
When the data will become available and for how long
Access will be 6 months after the results are printed.
To whom data/document is available
ll Physicians and residents of the department of
Under which criteria data/document could be used
After obtaining permission from the deputy research of group
From where data/document is obtainable
Person responsible for scientific accountability of study
What processes are involved for a request to access data/document
First approved by the Research Vice-President
Comments