

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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 Loss, 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)

Phone

+98 41 3655 8304

Email address

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

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohsen Mohammad Rahimi

Street address

Central building of Tabriz University of Medical Sciences, Golgasht avenue, Azadi street

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Email

mm.rahimi1357@gmail.com

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

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohsen Amjadi

Position

Associate professor/ Urologist

Latest degree

Specialist

Other areas of specialty/work

Urology

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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

All 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**Person responsible for updating data****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

Urology

Street address

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