Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness of using Surgicel in reducing bleeding in patients undergoing suprapubic simple open prostatectomy

Protocol summary

Study aim
Determining the effectiveness of using Surgicel in reducing bleeding in patients undergoing suprapubic simple open prostatectomy

Design
A randomized, single-blind, clinical trial, with the parallel groups, Phase 3 on 54 patients

Settings and conduct
Candidate patients for suprapubic simple open prostatectomy referred to Al-Zahra and Khorshid hospitals in Isfahan will be included in the study and randomly divided into 2 groups. In the first group, the surgery will be performed according to the standard techniques of suprapubic simple open prostatectomy, but after removing the prostate adenoma inside the prostate cavity, Surgicel will be used. In the second group, all surgical procedures will be performed according to the standard technique of suprapubic simple open prostatectomy, and Surgicel will not be used. Then hemoglobin, hematocrit, and bleeding during and after surgery will then be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients candidate for suprapubic simple open prostatectomy; consent to participate in the study. Exclusion criteria: a history of any prostate surgery; use of antiplatelets and anticoagulants; history of inherited bleeding diseases.

Intervention groups
Intervention group 1: In this group, the surgery will be performed according to the standard techniques of suprapubic simple open prostatectomy, but after removing the prostate adenoma inside the prostate cavity, Surgicel will be used. Control group: all surgical procedures will be performed according to the standard technique of suprapubic simple open prostatectomy, and Surgicel will not be used.

Main outcome variables
hemoglobin; Hematocrit; Bleeding volume

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N47**
Registration date: **2021-10-29, 1400/08/07**
Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**
Update count: **0**

Registration date
2021-10-29, 1400/08/07

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 0000 0000

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asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-21, 1400/08/30

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effectiveness of using Surgicel in reducing bleeding in patients undergoing suprapubic simple open prostatectomy

Public title
The effectiveness of using Surgicel in reducing bleeding in patients undergoing prostatectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate patients for suprapubic simple open prostatectomy Satisfaction to participate in the study
Exclusion criteria:
History of any prostate surgery Consumption of anti-platelets and anticoagulants History of hereditary bleeding diseases
Age
No age limit
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 54 eligible patients will be randomly selected. For this, the letter A is written on 27 sheets, and the letter B is written on 27 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the present study, the surgeon will be aware of the type of surgery in each of the two groups, but the patient and the evaluator (data collector) will not be aware of the type of surgery in each group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2021-07-16, 1400/04/25
Ethics committee reference number
IR.MUI.MED.REC.1400.320

Health conditions studied

1

Description of health condition studied
Suprapubic simple open prostatectomy
ICD-10 code
N52.34
ICD-10 code description
Erectile dysfunction following simple prostatectomy

Primary outcomes

1

Description
Hemoglobin
Timepoint
Before surgery, immediately, 24 and 48 hours after surgery
Method of measurement
Blood test

2

Description
Hematocrit
Timepoint
Before surgery, immediately, 24 and 48 hours after surgery
Method of measurement
Blood test

Secondary outcomes

1

Description
Bleeding volume
Timepoint
During and after surgery
Method of measurement
The amount of blood sucked

Intervention groups

1

Description
Intervention group: In this surgical group, suprapubic simple open prostatectomy will be performed according to standard techniques, but after removing the prostate adenoma inside the prostate cavity, Surgicel will be used. In this way, for a prostate weighing 75 grams, two pieces and with the increase in the weight of the prostate, for every 25 grams of weight gain, an additional number of Surgicel will be placed inside the prostate cavity and other steps will be performed until the end of surgery with standard techniques.
Category
Treatment - Surgery

2

Description
Control group: all surgical procedures will be performed according to the standard technique of suprapubic simple open prostatectomy, and Surgicel will not be used.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Reza Kazemi
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Hezar Jarib Street.
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2

Recruitment center
Name of recruitment center
Khorshid hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Reza Kazemi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available