

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of short-term complications of hemostatic powders and surgical on retrovesical bleeding during hysterectomy

#### Protocol summary

##### Study aim

Comparison of short-term complications of hemostatic powders and Surgicel on retrovesical bleeding during hysterectomy

##### Design

This clinical trial is phase3; randomized with software; without blinding in which 46 patient who are candidates for abdominal hysterectomy divided into two groups.

##### Settings and conduct

The research is carried out at Hajar Hospital in Shahrekord and there is no blinding

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patient candidate for elective abdominal hysterectomy; age range 70-40 years. Non inclusion criteria: pregnancy and taking ocp; history of systemic diseases ; inherited or acquired coagulation disorders; history of ischemic heart disease; history of taking anticoagulants and effective on bleeding ; smoking and alcohol; need to get blood and its products; need to have surgery again

##### Intervention groups

Intervention group 1: Surgicel and cauter are used topically during bleeding. Intervention group 2: ChitoHem and cauter are used topically during bleeding. All drugs are manufactured by Johanson & Johanson Company.

##### Main outcome variables

Bleeding

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200316046787N1**

Registration date: **2020-03-24, 1399/01/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-24, 1399/01/05**

Update count: **0**

##### Registration date

2020-03-24, 1399/01/05

##### Registrant information

###### Name

shirin moosavi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 3222 0016

###### Email address

mosavi@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-20, 1399/01/01

##### 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 short-term complications of hemostatic powders and surgical on retrovesical bleeding during hysterectomy

##### Public title

Comparison of hemostatic powders and surgical on behind bladder bleeding during hysterectomy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patient candidate for elective abdominal hysterectomy

Age range 40-70 years

**Exclusion criteria:**

Need to have surgery again  
Need to get blood and its products  
pregnancy and taking OCP  
history of systemic diseases  
history of inherited or acquired coagulation disorders  
history of ischemic heart disease  
history of taking anticoagulants and effective on bleeding  
smoking and alcohol drinking

**Age**

From **40 years** old to **70 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The random allocation of the participants to the intervention 1 and 2 groups will be done using random allocation software. Then, some envelopes will be prepared according to the number of participants in the study. Then number 1 will be recorded on the first envelope, number 2 on the second envelope, and etc. The sequence of assignment of the participants will be determined by the software and each assignment will be put inside each envelope respectively. At the time of study running, the specified envelope for each individual will be opened and the individual will be assigned to one of the intervention 1 or intervention 2 groups according to the option recorded inside the envelope.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahrekord University of Medical Sciences

**Street address**

Vice Chancellor of Research and Technology,  
Shahrekord University of Medical Sciences, Kashani  
boulevard

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8818718791

**Approval date**

2019-02-03, 1397/11/14

**Ethics committee reference number**

IR.SKUMS.REC.1397.256

**Health conditions studied**

1

**Description of health condition studied**

hysterectomy

**ICD-10 code**

N85

**ICD-10 code description**

Other noninflammatory disorders of uterus, except cervix

**Primary outcomes**

1

**Description**

hematocrit

**Timepoint**

12 hours after surgery

**Method of measurement**

Complete blood count test (CBC)

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention grou 1:Surgicel and cauter are used topically during bleeding. All drugs are manufactured by Johanson & Johanson Company

**Category**

Treatment - Drugs

2

**Description**

Intervention group2: ChitoHem and cauter are used topically during bleeding. All drugs are manufactured by Johanson & Johanson Company

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Hajar Hospital of Shahrekord

**Full name of responsible person**

Lobat Jafarzadeh

**Street address**

Hajar Hospital affiliated to Shahrekord University of Medical Sciences, Parastar Avenue, Shahrekord

**City**

Shahrekord

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**Postal code**

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+98 38 3222 0016

**Email**

jafarzade@skums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Mehraban Sadeghi

**Street address**

Vice Chancellor of Research and Technology, Shahrekord University of Medical Sciences ,Kashani boulevard, Shahrekord

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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**

Shahre-kord 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**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Lobat Jfarzadeh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Hajar Hospital of Shahrekord University of Medical Sciences, Parastar street, Shahrekord

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

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Lobat Jafarzade

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**Latest degree**

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Shahre-kord University of Medical Sciences

**Full name of responsible person**

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**Latest degree**

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**Other areas of specialty/work**

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**Phone**

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**Email**

jafarzade@skums.ac.ir

**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**

No more 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