

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

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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

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

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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

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