

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of oral Clonidine on reducing bleeding during hysterectomy

Protocol summary

Study aim

Determining the effect of oral clonidine on reducing bleeding during hysterectomy surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. Random Allocation software was used for randomization.

Settings and conduct

In the present double-blind clinical trial study, 70 patients who are candidates for elective abdominal hysterectomy in Hajar Hospital in Shahrekord are included in the study. Resident during operation and gas counting and statistical consultant is unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. age 60-40 years 2. Patient informed consent 3. No pregnancy and use of birth control pills 4. Absence of systemic diseases and inherited or acquired coagulation disorders 5. No history of ischemic heart disease 6. No history of taking anticoagulants that affect bleeding 7. No smoking and alcohol 8. Known insensitivity to clonidine 9. No history of repeated abdominal surgeries and the presence of abdominal adhesions Exclusion criteria: 1. Need for reoperation 2. The patient withdraws from the study or does not cooperate for further follow-up. 3. Raynaud's syndrome, porphyria, renal dysfunction

Intervention groups

Intervention group: Clonidine tablets 0.2 (mg) 90 minutes before surgery Control group: placebo tablets 90 minutes before surgery

Main outcome variables

The amount of bleeding during the operation; Hemoglobin and hematocrit before and after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211117053086N1**

Registration date: **2022-01-18, 1400/10/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-18, 1400/10/28**

Update count: **0**

Registration date

2022-01-18, 1400/10/28

Registrant information

Name

Bibi Fatemeh Alavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 8575

Email address

eslami@ualberta.ca

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-05-21, 1401/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral Clonidine on reducing bleeding during hysterectomy

Public title

Evaluation of the effect of oral Clonidine on reducing bleeding during hysterectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patient informed consent
No pregnancy and use of birth control pills
Absence of systemic diseases and inherited or acquired coagulation disorders
No history of ischemic heart disease
No history of taking anticoagulants that affect bleeding
No smoking and alcohol
Known insensitivity to clonidine
No history of repeated abdominal surgeries and the presence of abdominal adhesions

Exclusion criteria:

Raynaud's syndrome
porphyria
Renal dysfunction

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects were selected by convenience sampling method and Random Allocation divided into two groups A and B using clonidine (0.2 mg) and placebo tablets, respectively using randomizer software (Fahmy Corporation, Randomizer 2016.6.0.56).

Blinding (investigator's opinion)

Double blinded

Blinding description

Resident (during operation and gas counting) and statistical consultant are unaware of the type of grouping (intervention or control)

Placebo

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 for Research and Technology,
Building No. 2, University Headquarters, Kashani Blvd.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2021-10-26, 1400/08/04

Ethics committee reference number

IR.SKUMS.REC.1400.178

Health conditions studied

1

Description of health condition studied

hysterectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bleeding rate

Timepoint

Immediately after surgery

Method of measurement

Visual estimation scale: The number of normal gases impregnated in blood is multiplied by 10 ml and long gases by 50 ml and the result is added to the volume of suctioned blood. Since this volume is included in the volume of rinsing fluids in the surgical area; It also reduces the amount of fluid consumed and the result is equal to the amount of actual blood loss of the patient.

Secondary outcomes

empty

Intervention groups

1

Description

The first group will be prescribed routine surgical preparations and clonidine tablets 0.2 (mg) 90 minutes before entering the operating room. This medicine will be provided by a Tolid-Daroo company.

Category

Prevention

2

Description

Control group: In the second group, routine procedures will be performed to prepare for surgery, and a placebo will be provided by Tolid-Daroo company. Placebo tablets will be given 90 minutes before surgery.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar hospital
Full name of responsible person
Lobat Jafarzadeh
Street address
Hajar hospital, Parastar st.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehraban Sadeghi
Street address
Vice Chancellor for Research, Building No. 2,
University Headquarters, Ayatollah KashaniBlvd.
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Sadeghi@skums.ac.ir
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
Bibi Fatemeh Alavi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Full name of responsible person
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Latest degree
Medical doctor
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)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Information is kept confidential

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

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

Information about the main outcome can be shared

When the data will become available and for how long

After publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using data to complete studies

From where data/document is obtainable

Shahrekord University of Medical Sciences, Dr. Lobat Jafarzadeh

What processes are involved for a request to access data/document

By examining the researcher's request and providing sufficient documentation of his research and the reason for using the data can be provided

Comments