

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the effect of general and spinal anesthesia on serum level of pro-inflammatory and anti-inflammatory factors after abdominal hysterectomy surgery: a non-randomized clinical trial

Protocol summary

Study aim

Determining the level of inflammatory, and anti-inflammatory in hysterectomy patients using general and spinal anesthesia.

Design

A non-randomized, single-blind, parallel-group, two-arm clinical trial (21 patients in each group).

Settings and conduct

The study will be a non-randomized, single-blind clinical trial at Afzalipur Hospital in Kerman. According to the medical considerations and the individual's desire, if it is clinically possible, the patients were placed in one of the study groups to receive spinal or general anesthesia before hysterectomy surgery. The principal investigator and data analyst were masked from patient allocation.

Participants/Inclusion and exclusion criteria

Patients who will undergo hysterectomy with different diagnoses are included in the study. Patients with a history of inflammatory and autoimmune disease, endocrine disorders, severe neurological disease, use of corticosteroids in the three months before surgery, or evidence of any infectious disease are excluded from the study.

Intervention groups

Patients in the intervention group received spinal anesthesia (20 µg Fentanyl, 20 µg Bupivacaine, and 10 µg Epinephrine) and patients in the control group received general anesthesia (0.01 mg of midazolam, 3 µg Fentanyl, and 5 mg/weight of Thiopental and 0.5 mg/weight of Atracurium) before operation.

Main outcome variables

serum level of inflammatory factors IL-2; IL 17; IL 6; TNF α serum level of non-inflammatory factors IL-10

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190819044559N4**

Registration date: **2023-01-31, 1401/11/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-31, 1401/11/11**

Update count: **0**

Registration date

2023-01-31, 1401/11/11

Registrant information

Name

Morteza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3223 5011

Email address

mortezahashemian@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of general and spinal

anesthesia on serum level of pro-inflammatory and anti-inflammatory factors after abdominal hysterectomy surgery: a non-randomized clinical trial

Public title

The effect of general and spinal anesthesia on the level of inflammatory factors in hysterectomy surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who will undergo hysterectomy with different diagnoses are included in the study.

Exclusion criteria:

Patients with a history of any type of inflammatory and autoimmune disease
History of endocrine diseases
Severe neurological disease
Corticosteroid use in the three months before surgery
Evidence of any infectious disease

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will be single-blinded. The outcome assessor and data analyst and researcher who must enter the data into the relevant checklist will be blinded to the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Afzalipour Hospital-
Kerman University of Medical Sciences

Street address

Close to Shahid Bahonar University, Imam Khomeyni

highway,

City

Kerman

Province

Kerman

Postal code

7616913911

Approval date

2022-10-18, 1401/07/26

Ethics committee reference number

IR.KMU.AH.REC.1401.154

Health conditions studied

1

Description of health condition studied

Inflammatory factors after hysterectomy

ICD-10 code

N93.9

ICD-10 code description

Abnormal uterine and vaginal bleeding, unspecified

Primary outcomes

1

Description

IL -17 serum level

Timepoint

Before intervention, 48 hours after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

2

Description

IL-2 serum level

Timepoint

Before intervention, 48 hours after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

3

Description

IL -6 serum level

Timepoint

Before intervention, 48 hours after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

4

Description

TNF - α serum level

Timepoint

Before intervention, 48 hours after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

5

Description

IL-10 serum level

Timepoint

Before intervention, 48 hours after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients receive spinal anesthesia (20 micrograms of fentanyl, 20 micrograms of bupivacaine and 10 micrograms of epinephrine).

Category

Treatment - Surgery

2

Description

Control group: Patients will receive general anesthesia (0.01 mg midazolam, 3 µg fentanyl, 5 mg/wt thiopental, and 0.5 mg/wt atracurium) before the procedure.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Morteza hashemian

Street address

Close to Shahid Bahonar University, Imam Khomeyni highway

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mortezahashemian@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpouafshar

Street address

Ebn-e Sina st, Jahad blvd.

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VCR@KMU.AC.IR

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Morteza Hashemian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Ladan Amirkhosravi

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available