

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of remifentanil on hemodynamic changes and laxity of patients undergoing complete abdominal hysterectomy

Protocol summary

Study aim

The effect of remifentanil on hemodynamic changes and laxity of patients undergoing complete abdominal hysterectomy

Design

This study will be a double-blind randomized clinical trial with factorial groups on 50 patients referred to Peymaniyeh Motahhari Hospital in Jahrom who undergo complete hysterectomy through the abdomen. Patients participating in the study will be divided into two groups by tossing coins.

Settings and conduct

Patients referred to Motahhari Hospital in Jahrom who will undergo complete hysterectomy through the abdomen will be included in the study. Patients participating in the study will be divided into two groups of remifentanil and control by tossing coins. The person participating in the study, the researcher and the data collector will be unaware of the type of drug used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients referred to Motahhari Hospital in Jahrom who underwent complete hysterectomy through the abdomen and expressed their consent to participate in the study. Non-entry conditions: includes patients who do not have hemodynamic stability and suffer from acute and chronic pain.

Intervention groups

Intervention group 1: To maintain anesthesia in this group, remifentanil infusion at a dose of $2 \mu\text{g} / \text{kg} / \text{hour}$ and propofol infusion at a dose of $200 \mu\text{g} / \text{kg} / \text{h}$ will be used. Intervention group 2: Propofol infusion at a dose of $200 \mu\text{g} / \text{kg} / \text{h}$ and N2O will be used as a control group to maintain anesthesia in this group.

Main outcome variables

Hemodynamic changes, patient relaxation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050976N9**

Registration date: **2022-02-16, 1400/11/27**

Registration timing: **prospective**

Last update: **2022-02-16, 1400/11/27**

Update count: **0**

Registration date

2022-02-16, 1400/11/27

Registrant information

Name

navid kalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 6085

Email address

k.navid@juma.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-08-01, 1401/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of remifentanil on hemodynamic changes and laxity of patients undergoing complete abdominal hysterectomy

Public title

The effect of remifentanyl on hemodynamic changes and laxity of patients undergoing complete abdominal hysterectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patient consent to study Anesthesia class one and two

Age 20 to 60 years

Exclusion criteria:

Existence of cervical malignancy History of diabetes or endometriosis History of neurological diseases Abnormal Pap smear Chronic pelvic pain History of heart disease or hypertension

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used. With the help of the online site (www.sealedenvelope.com/simple-randomiser/v1/lists) randomization, 2 blocks of 25 are created. In each block, randomly classified, 25 patients are assigned to remifentanyl group and 25 patients to control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding in the present study, the double-blind method is used in such a way that 1- the person who reviews the results and 2- the person who performs the injections have no information about which patients received remifentanyl and which patients received normal saline as a control group. The drugs are drawn in the same syringes and separated only by the letters A and B and will be given to the injector.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jahrom University of Medical Sciences

Street address

Jahrom University of Medical Sciences, Shahid Motahari Boulevard, Jahrom

City

Jahrom

Province

Fars

Postal code

7167758256

Approval date

2022-02-05, 1400/11/16

Ethics committee reference number

IR.JUMS.REC.1400.091

Health conditions studied

1

Description of health condition studied

Transe abdominal hysterectomy

ICD-10 code

N99.3

ICD-10 code description

Prolapse of vaginal vault after hysterectomy

Primary outcomes

1

Description

blood pressure

Timepoint

قبل از عمل، بلافاصله بعد از اینداکشن، 5 دقیقه بعد از عمل، 15 دقیقه بعد از عمل و 30 دقیقه بعد از عمل و به محض ورود به ریکاوری

Method of measurement

monitoring

2

Description

Heart Rate

Timepoint

Before surgery, immediately after induction, 5 minutes after surgery, 15 minutes after surgery and 30 minutes after surgery and as soon as recovery begins

Method of measurement

monitoring

3

Description

Being relaxed

Timepoint

At times 15, 30, 45, 60, 90, 120 and 180 during the operation will be examined as a Likert scale (low, medium, high and very high).

Method of measurement

Surgeon satisfaction with the patient's muscle relaxation

Secondary outcomes

1

Description

Bleeding

Timepoint

During the operation at times 15, 30, 45, 60, 90, 120 and 180

Method of measurement

1. In terms of gas (surgical gas with a size of 10 by 16 cm (4 inches): 10 ml and each langaz: 100 ml), very wet langaz: 150 ml / 2. According to the amount of blood in the suction (without Calculation of washing serum)

Intervention groups

1

Description

Intervention group 1: To maintain anesthesia in this group, remifentanil infusion at a dose of $2 \mu\text{g} / \text{kg} / \text{hour}$ and propofol infusion at a dose of $200 \mu\text{g} / \text{kg} / \text{h}$ will be used.

Category

Treatment - Drugs

2

Description

Control group: Propofol infusion at a dose of $200 \mu\text{g} / \text{kg} / \text{hour}$ and N₂O will be used as a control group to maintain anesthesia in this group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital of Jahrom city

Full name of responsible person

Navid Kalani

Street address

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Jahrom

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71677251542

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Navidkalani@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Kavous Solh Joo

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Email

navidkalani@ymail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

Undecided - It is not yet known if there will be 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

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