Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 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 µg / kg / hour and propofol infusion at a dose of 200 µg / kg / h will be used. Intervention group 2: Propofol infusion at a dose of 200 µg / kg / 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)

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+98 71 5433 6085

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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 remifentanil 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 remifentanil 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 remifentanil 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 µg / kg / hour and propofol infusion at a dose of 200 µg / kg / h will be used.
Category
Treatment - Drugs

2

Description
Control group: Propofol infusion at a dose of 200 µg / kg / 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
Jahrom, Shahid Motahari Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
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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
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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Latest degree

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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