

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effects of remifentanyl and dexmedetomidine on recovery profile of patients after hysterectomy operation under anesthesia with venous propofol

Protocol summary

Summary

• Objectives: Comparison of the effects of remifentanyl and dexmedetomidine on recovery profile of patients after hysterectomy operation under anesthesia with venous propofol • Design: patients referring to the Firozgar hospital who are candidate for hysterectomy provided informed consent will be randomly assigned into two groups of dexmedetomidine and remifentanyl. Study is phase 1/2, double-blinded and single center. • Setting and conduct: in this double-blinded randomized clinical trial, patients candidate for hysterectomy will be recruited according to the inclusion and exclusion criteria. All patients will sign informed consent forms. Anesthesia induction will be performed and the patients will receive 1 µg/kg of dexmedetomidine in 15 minutes and then 2 µg/kg/hour in the dexmedetomidine group and remifentanyl 1 µg/kg/minute in the remifentanyl group as infusion until the end of operation. • Participants including major eligibility criteria: patients candidate for elective hysterectomy operation in Firozgar hospital with ASA I-II grade provided informed consent are included. Patients above 70 years of age, emergency operation, patients with cardiopulmonary, renal, hepatic, diabetes, hypertension, obesity, difficult airway, lactating women, sleep apnea and psychological diseases will be excluded. • Intervention: drugs remifentanyl and dexmedetomidine • Main outcome measures: anesthesia and operation duration, ETCO₂, extubation time, recovery time, bradycardia, hypotension and Aledret scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102731487N6**
Registration date: **2017-11-20, 1396/08/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

مهرداد Mesbah kiaei

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 346 5866

Email address

dr.mmesbah@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research of Iran University of Medical Sciences

Expected recruitment start date

2017-10-31, 1396/08/09

Expected recruitment end date

2018-04-23, 1397/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of remifentanyl and dexmedetomidine on recovery profile of patients after

hysterectomy operation under anesthesia with venous propofol

Public title

Comparison of the effects of two anesthetics on recovery profile of patients after hysterectomy operation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients candidate for elective hysterectomy operation in Firozgar hospital; ASA I-II grade; informed consent Exclusion criteria: patients above 70 years of age; emergency operation; patients with cardiopulmonary disease; renal disease; hepatic disease; diabetes; hypertension; obesity; difficult airway; lactating women; sleep apnea; psychological diseases

Age

From **2 days** old to **70 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients will be randomly allocated into two groups using block randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of the Iran University of Medical Sciences

Street address

Next to Milad Tower, Hemmat highway

City

Tehran

Postal code

15459-13487

Approval date

2017-10-09, 1396/07/17

Ethics committee reference number

IR.IUMS.FMD.REC1396.130417

Health conditions studied

1

Description of health condition studied

Hysterectomy

ICD-10 code

Z90.7

ICD-10 code description

Acquired absence of genital organ(s)

Primary outcomes

1

Description

Consciousness

Timepoint

After recovery

Method of measurement

Aldrete questionnaire

Secondary outcomes

1

Description

Hemodynamic parameters

Timepoint

Every two hours from beginning of the operation and after the operation

Method of measurement

Barometer

Intervention groups

1

Description

Intervention group 1: 1 µg/kg of dexmedetomidine in 15 minutes and then 2 µg/kg/hour till the end of operation

Category

Treatment - Drugs

2

Description

Intervention group 2: 1 µg/kg/minute of remifentanyl until end of the operation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar hospital

Full name of responsible person

Dr Faranak Rokhtabnak

Street address

Behafarin st., Karim Khan Ave.

City

Tehran

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr Faranak Rokhtabnak

Position

Faculty member

Other areas of specialty/work**Street address**

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice-chancellor for Research, Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Kazem Malakouti

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Office of Vice-chancellor for Research, Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor for Research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Faculty member

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary
empty