Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the effect of two different doses of dexmedetomidine and propofol in sedation during surgery; Hemodynamic changes and postoperative complications in patients undergoing ovarian puncture surgery

Protocol summary

Study aim
Determining and comparing the effect of two different doses of dexmedetomidine and propofol in sedation during surgery in patients undergoing ovarian puncture surgery

Design
A randomized, triple-blinding clinical trial, with the parallel groups, Phase 3 on 96 patients

Settings and conduct
In this three-blind randomized clinical trial study, 96 eligible patients referred to Isfahan Shahid Beheshti Hospital will be included and will be randomly divided into three groups. For patients in three groups, dexmedetomidine 0.5 and 1 µg/kg and propofol 50 µg/kg will be prescribed respectively. In this study, the patient, the researcher, and the statistical analyst will have no knowledge of the type of intervention. Then the degree of sedation and hemodynamic parameters of the patients will be evaluated between the three groups.

Participants/Inclusion and exclusion criteria
The inclusion criteria include infertile women candidates for puncture operation with IVF/ICSI indication, in the age group of 25 to 43 years, with ASA I or II, consent to enter the study. Exclusion criteria include having an allergy to any drug used, having a history of comorbidity.

Intervention groups
Control group: in this group, propofol induction of anesthesia 50 µg/kg per minute is prescribed. First intervention group: In this group, dexmedetomidine bolus dose of 0.5 µg/kg is prescribed for induction of anesthesia, and dexmedetomidine dose of 0.5 µg/kg per minute is prescribed for anesthesia maintenance. The second intervention group: In this group, a bolus dose of dexmedetomidine 1 µg/kg is prescribed for induction of anesthesia, and a dose of dexmedetomidine 1 µg/kg per minute is prescribed for anesthesia maintenance.

Main outcome variables
Heart rate; Systolic blood pressure; Diastolic blood pressure; Respiratory rate; Percentage of oxygen saturation; Degree of sedation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N73**
Registration date: **2024-02-16, 1402/11/27**
Registration timing: **prospective**

Last update: **2024-02-16, 1402/11/27**
Update count: **0**

Registration date
2024-02-16, 1402/11/27

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 0000 0000

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-20, 1403/01/01

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of two different doses of dexmedetomidine and propofol in sedation during surgery; Hemodynamic changes and postoperative complications in patients undergoing ovarian puncture surgery

Public title

Comparison of the effects of two different doses of dexmedomidine and propofol in sedation during ovarian surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women candidates for puncture operation with IVF/ICSI indication Age 25 to 43 years With ASA I or II Consent to enter the study

Exclusion criteria:

Having an allergy to any drug used Having a history of diseases such as epilepsy and gastric reflux and a history of severe cardiovascular disease and the presence of atrial block or stroke

Age

From **25 years** old to **43 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 96 eligible patients are randomly selected. For this, the letter A is written on 32 sheets, the letter B is written on 32 sheets, the letter C is written on 32 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of three groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to achieve the triple-blind study, different doses of dexmedomidine and propofol will be prepared daily by the operating room nurse (without the researcher's awareness) and placed in the bag and will be labeled A, B, and C. And is given daily to the anesthesiologist (researcher). Therefore, the patient, the Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2023-12-27, 1402/10/06

Ethics committee reference number

IR.MUI.MED.REC.1402.362

Health conditions studied

1

Description of health condition studied

Ovarian puncture surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sedation

Timepoint

Before the intervention and then 5, 10, 15 and 30 minutes after the intervention and then every 15 minutes during recovery until discharge

Method of measurement

Richmond sedation score scale (RASS) as a score of +4 to -5

2

Description

Hear rate

Timepoint

Before the intervention and then 5, 10, 15 and 30 minutes after the intervention and then every 15 minutes during recovery until discharge

Method of measurement

Monitoring device

3

Description

Diastolic blood pressure

Timepoint

Before the intervention and then 5, 10, 15 and 30 minutes after the intervention and then every 15 minutes during recovery until discharge

Method of measurement

Monitoring device

4

Description

Systolic blood pressure

Timepoint

Before the intervention and then 5, 10, 15 and 30 minutes after the intervention and then every 15 minutes during recovery until discharge

Method of measurement

Monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Control group: in this group, propofol induction of anesthesia 50 µg/kg per minute is prescribed.

Category

Treatment - Drugs

2

Description

First intervention group: In this group, dexmedetomidine bolus dose of 0.5 µg/kg is prescribed for induction of anesthesia, and dexmedetomidine dose of 0.5 µg/kg per minute is prescribed for anesthesia maintenance.

Category

Treatment - Drugs

3

Description

The second intervention group: In this group, a bolus dose of dexmedetomidine 1 µg/kg is prescribed for induction of anesthesia, and a dose of dexmedetomidine 1 µg/kg per minute is prescribed for anesthesia maintenance.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mohammadreza Habibzadeh

Street address

Motahari Street.

City

Isfahan

Province

Isfehan

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8174673461

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammadreza Habibzadeh
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Anesthesiology
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Isfehan
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zv.azadani@ymail.com

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
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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available