Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of two drug combinations remifentanil propofol and ketamine propofol on hemodynamic parameters and reproductive outcome after intracytoplasmic sperm injection in patients undergoing oocyte retrieval with general anesthesia a double blind randomized clinical trial

Protocol summary

Study aim

The aim of this study was to compare the effects of remifentanil propofol and ketamine propofol on hemodynamic parameters, recovery time and intracytoplasmic sperm injection outcome in patients undergoing general anesthesia for oocyte retrieval.

Design

An controlled, double blind, randomized clinical trial with a parallel-group design of 200 patients, enrolled between 2021 and 2023.

Settings and conduct

The present double-blind study will be performed at Mehr Medical Institute. Induction of anesthesia will be done in group remifentanil propofol with propofol 2 mg/kg and remifentanil 1 to 1.5 µg/kg and in the group ketamine propofol, ketofol containing propofol 1 to 1.5 mg/kg with 0.5 mg/kg of ketamine. Lidocaine 40 mg is prescribed to reduce the pain of propofol injection. The patient knows exactly two drugs and generally knows the methods and drugs, but does not know exactly which drug he has received. The analyzer is also unaware of the two groups. The specialist doctor is aware of two groups.

Participants/Inclusion and exclusion criteria

Inclusion: American Society of Anesthesiologists Classification grade I and II Age less than 42 years Exclusion: Signs of poor ovarian response Preimplantation genetic screening cycles History of cardiorespiratory disease Chronic drug use Allergy to anesthetics

Intervention groups

Intervention group: Induction of anesthesia in intervention group will be done with propofol 1 to 1.5 mg/kg and ketamine 0.5 mg/kg Control group: Induction of anesthesia in control group will be done with propofol 2 mg/kg and remifentanil 1 to 1.5 µg/kg.

Main outcome variables

Fertilization rate, clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120110008677N7**
Registration date: **2021-10-29, 1400/08/07**
Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**
Update count: **0**

Registration date

2021-10-29, 1400/08/07

Registrant information

Name
Farnoush Farzi

Name of organization / entity
Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 13 1322 5624

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-21, 1400/08/30

Expected recruitment end date
2023-03-21, 1402/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of two drug combinations remifentanil propofol and ketamine propofol on hemodynamic parameters and reproductive outcome after intracytoplasmic sperm injection in patients undergoing oocyte retrieval with general anesthesia a double blind randomized clinical trial

Public title
The effect of anesthesia agents on intracytoplasmic injection of sperm outcome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
American Society of Anesthesiologists Classification grade I and II Age less than 42 years
Exclusion criteria:
Preimplantation genetic screening cycles Signs of poor ovarian response History of cardiorespiratory disease Chronic drug use Allergy to anesthetics
Age
From **18 years** old to **41 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be done using computer software. The list of blocks will be written and numbers will be assigned to them (AABB (1) - ABAB (2) -ABBA (3) - BBAA (4) - BABA (5) - BAAB (6)), then random numbers between one and six (For example, 1 4 5, etc.) will be select and finally the treatment allocation list based on previous random numbers (AABB, BBAA, BABA, etc.) will be specified.
Blinding (investigator's opinion)
Double blinded
Blinding description
At the anesthesia visit, all the conditions of the study will be explained by a respected anesthesiologist. If the patient wishes to participate in the study, written consent will be obtained. The patient knows exactly two drugs and generally knows the methods and drugs, but does not know exactly which drug he has received. The analyzer is also unaware of the nature of the two groups. The specialist doctor is aware of two groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committees of Guilan university of medical sciences
Street address
Shahid Siadati Ave, Namjoo St, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
6694941446
Approval date
2021-09-15, 1400/06/24
Ethics committee reference number
IR.GUMS.REC.1400.259

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Fertilization rate
Timepoint
One day after intracytoplasmic injection of sperm
Method of measurement
Stereo microscope

2

Description
Clinical pregnancy
Timepoint
Six to seven weeks after embryo transfer

Method of measurement
Ultrasonography

Secondary outcomes

1

Description
Response time to voice commands
Timepoint
Following discontinuation of anesthesia agents
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Induction of anesthesia in group ketamine propofol, ketofol drug containing: propofol 1-1.5 mg/kg with 0.5 mg/kg ketamine. Lidocaine 40 mg is prescribed to reduce the pain of propofol injection. Anesthesia will be continued with incremental doses of 30 to 50 mg propofol as needed.
Category
Treatment - Drugs

2

Description
Control group: Induction of anesthesia in group remifentanil propofol will be performed with remifentanil 1 to 1.5 µg/kg and propofol 2 mg/kg. Lidocaine 40 mg is prescribed to reduce the pain of propofol injection. Anesthesia will be continued with incremental doses of 30 to 50 mg propofol as needed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehr Medical Institute
Full name of responsible person
Farnoush Farzi
Street address
Mehr Medical Institute, Ershad St, Ansari Blv, Rasht, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mehr Medical Institute
Full name of responsible person
Marzieh Mehrafza
Street address
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marzieh.mehrafza@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mehr Medical Institute
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Mehr medical institute
Full name of responsible person
Farnoush Farzi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Mehr Medical Institute, Ershad St, Ansari Blv, Rasht, Iran
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Person responsible for updating data

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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