

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparsion of Midazolam and Dexmedetomidine for pain relief and decreasing fallopian tubes spasm during and after hysterosalpingography in infertile women

Protocol summary

Summary

The aim of this study is comparison of Midazolam and Dexmedetomidine for pain relief and decreasing fallopian tubes spasm during and after hysterosalpingography in infertile women. This study is a double blind clinical trial. 102 women will be divided into two groups randomly (randomization will be done by random numbers table). We will inject 0.4 milligram per kilogram Midazolam, 3-4 minutes before surgery and we will continue infusion of normal slain 0.5 microgram per kilogram in first group. In second group we will inject 1 microgram in kilogram Dexmedetomidin and we will continue treatment with the infusion of 0.5 microgram per kilogram Dexmedetomidine. We will start the process when sedation is 2 and 3in Ramsy scales. We will determine pain score using visual analog scale. We will record presence or absence of spasm of fallopian tubes during hysterosalpingography. Inclusion criteria: being female; infertility; being at the age of 20 to 45 years. Exclusion criteria: Contraindications for the use of Dexmethomidine and Midazolam; uterine malignancy; vaginal bleeding; history of cervical surgery; pelvic inflammation; use of any kind of housing before hysterosalpingography; obstruction of fallopian tubes greater than 45 minutes; Unstable hydrodynamic symptoms during hysterosalpingography; Vaginal delivery; Secondary infertility. Primary outcomes: pain; spasm in fallopian tube.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081520258N57**

Registration date: **2017-10-12, 1396/07/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-12, 1396/07/20

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2017-05-15, 1396/02/25

Expected recruitment end date

2019-05-15, 1398/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion of Midazolam and Dexmedetomidine for pain relief and decreasing fallopian tubes spasm during and after hysterosalpingography in infertile women

Public title

Pain relief and decreasing fallopian tubes spasm during and after hysterosalpingography in infertile women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: infertility; 20 to 45 years
Exclusion criteria: Contraindications for the use of Dexmethomidine and Midazolam; uterine malignancy; vaginal bleeding; history of cervical surgery; pelvic inflammation; use of any kind of pain reliever before hysterosalpingography; fallopian tubes obstruction.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

randomize by random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Postal code

38149578558

Approval date

2017-05-15, 1396/02/25

Ethics committee reference number

IR.ARAKMU.REC.1396.14

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Pain

Timepoint

During hysterosalpingography

Method of measurement

Visual Analogue Scale

2

Description

Spasm

Timepoint

During hysterosalpingography

Method of measurement

Graphy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 2: We will inject 1 micro gram in kilogram Dexmedetomidin and we will continue drug therapy by 0/5 micro gram in kilogram Dexmedetomidine through infusion.

Category

Treatment - Drugs

2

Description

Intervention group 1: We will inject 0/4 milligram in kilogram Midazolam, single dose, 3-4 minute before surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private radiology clinic

Full name of responsible person

Dr Fatemeh Safi
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Web page address

Person responsible for scientific inquiries

Contact

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
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Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
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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
Vice chancellor for research, Arak 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
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Full name of responsible person
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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