

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of hyoscine on pain and fallopian tubes spasm during and after hysterosalpingography in infertile women

Protocol summary

Summary

Infertility is a common problem in gynecology. Hysterosalpingography (HSG) is one of the main diagnostic procedures that use for evaluation of uterine and fallopian tubes openness. While this procedure is a non invasive and don't need to anesthesia and cervical dilation, however patients have discomfort and lower abdominal pain during and after HSG. It is due to cervical manipulation, uterine distension and peritoneal sensitivity. Pain during this procedure has negative effect on patient's adaption with treatment and physicians trying to overcome to this undesirable situation. Hyoscine is one of drugs that its effect on pain and spasm of fallopian tubes has not studied. So, it is necessary that we perform the study that measures the effect of Hyoscine on pain and spasm during and after HSG in infertile women. Main objective of this study is identification of hyoscine effect on pain and spasm during and after HSG in infertile women. Patients will allocate in intervention and control groups. In the intervention group, 15 minute before the procedure, Ampoule hyoscine 20mg/cc will inject intramuscularly. In control group, Patient will receive 1cc placebo (distilled water) intramuscularly before the procedure. After injection of dye, patients recorded their severity of pain in the numeric analog scale. Then HSG will done and after the review will determine whether or not another graphy should be prepared. Presence or absence of fallopian tube spasm at this stage will be determined. If contrast does not pass through the fallopian tube after first and second injection, spasm will determined. Thirty minutes after completion of the procedure, the pain will be examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021132455N2**

Registration date: **2017-06-26, 1396/04/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Mahboubeh Rezaei

Name of organization / entity

Kashan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2017-09-05, 1396/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hyoscine on pain and fallopian tubes spasm during and after hysterosalpingography in infertile women

Public title

Effect of hyoscine on pain and spasm during uterine graphy

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: duration of HSG more than 45 min; unstable hemodynamic sings during HSG. Negative inclusion criteria: contraindication of hyoscine use; uterine malignancy; vaginal bleeding; history of cervical surgery; pelvic inflammatory disease; use of any analgesic drugs before HSG; fallopian tube obstruction
Inclusion criteria: infertile women; age between 20 - 45 years; Having informed consent; performing the procedure (HSG) by a resident

Age

From **75 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of medical Sciences

Street address

Vice chancellor for research, 3th floor, Emam Mousa Kazem building, University complex, Basij Sq, Arak, Iran

City

Arak

Postal code

Approval date

2016-04-25, 1395/02/06

Ethics committee reference number

IR.ARAKMU.REC.1395.37

Health conditions studied

1

Description of health condition studied

Pain and Spasm in Fallopian tubes

ICD-10 code

N83.9

ICD-10 code description

Noninflammatory disorder of ovary, fallopian tube and broad ligament, unspecified

Primary outcomes

1

Description

Pain

Timepoint

During and after hysterosalpingography

Method of measurement

Numeric rating scale

2

Description

Spasm

Timepoint

During and after hysterosalpingography

Method of measurement

Graphy

Secondary outcomes

empty

Intervention groups

1

Description

In this study, after determination of sample size, patient will allocate in two groups: intervention and control groups according to table of random numbers. All of participants must be in their follicular phase of menstruation cycle. This study is double blind and two groups of patients and researcher will not know about the hyoscine or placebo groups.

Category

Treatment - Drugs

2

Description

In the intervention group, 15 minute before the procedure, hyoscine 20 mg/cc will inject intramuscularly

Category

Treatment - Drugs

3

Description

In control group, Patient will receive 1cc placebo (distilled water) intramuscularly

Category

Treatment - Drugs

4

Description

After injection of dye, patients recorded their severity of pain in the numeric analog scale. Then HSG will done and after the review will determine whether or not another graphy should be prepared. Presence or absence of fallopian tube spasm at this stage will be determined. If contrast does not pass through the fallopian tube after first and second injection, spasm will determined. Thirty minutes after completion of the procedure, the pain will be examined.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiology department, Valieasr hospital, Arak
University of Medical Sciences, Arak, Iran

Full name of responsible person

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak university of Medical Sciences

Full name of responsible person

Vice Chancellor for Research Office

Street address

Vice chancellor for research, 3th floor, Emam Mousa
Kazem building, University complex, Basij Sq, Arak,
Iran

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Arak University of Medical Sciences

Full name of responsible person

Marzieh Rezaei

Position

General physician, Radiology Assistant

Other areas of specialty/work

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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