Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of evening primrose on cervix dilatation and pain during and after hysterosalpangiography in infertile women

Protocol summary

Summary

The aim of this study is evaluation of the effect of evening primrose on dilatation of cervix and pain during and after hysterosalpangiography. This study is a double blind clinical trial. This study is double blind because researcher and patients don't aware from this grouping. In this study 66 patients who are candidate for hysterosalpangiography participate in the study. We will divide patients into two groups randomly through random number table. We prescribe evening primrose produced by Barij, 1000 milligram oral tab, BD, from three days before hysterosalpangiography to start of process in intervention group. We prescribe placebo 1000 milligram oral tab, BD, from three days before hysterosalpangiography in control group. We record pain during and after hysterosalpangiography and 4 hours after hysterosalpangiography. We record fallopian tube spasm during hysterosalpangiography. Inclusion criteria: infertility; being at the age of 20 to 40 years; female; candidate for hysterosalpangiography; hysterosalpingography performing by one researcher resident in training. Exclusion criteria: Severe dysmenorrhea; Pelvic infection; history of cervical stenosis; Sensitization to the drug; hysterosalpingography duration more than 45 minutes; Unstable hydrodynamic symptoms during hysterosalpingography; Vaginal delivery; Secondary infertility.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070520258N52**
Registration date: **2017-09-12, 1396/06/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-12, 1396/06/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor and Research,Arak University of Medical Sciences

Expected recruitment start date

2017-05-31, 1396/03/10

Expected recruitment end date

2019-03-12, 1397/12/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of evening primrose on cervix dilatation and pain during and after hysterosalpangiography in infertile women

Public title

Effect of evening primrose on pain during hysterosalpangiography in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:infertility; 20 to 40 years; female; candidate for hysterosalpangiography; hysterosalpingography should be done just by one researcher resident. Exclusion criteria: Severe dysmenorrhea; Pelvic infection; history of cervical stenosis; Sensitization to intervention drug; duration of hysterosalpingography greater than 45 minutes; Unstable hydrodynamic symptoms during hysterosalpingography; Vaginal delivery; Secondary infertility

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: **66**

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

Dr Mohammad Rafiei, Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City

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Postal code

38149578558

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.ARAKMU.REC.1396.42

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 and after hysterosalpangiography and 4 hours after hysterosalpangiography

Method of measurement

Visual Analogue Scale

2

Description

Tube spasm

Timepoint

During hysterosalpangiography

Method of measurement

observation by hysterosalpangiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We prescribe evening primrose produced by Barij, 1000 milligram oral tab, BD, from three days before hysterosalpangiography to start of process in intervention group.

Category

Treatment - Drugs

2

Description

Control group: We prescribe placebo 1000 milligram oral tab, BD, from three days before hysterosalpangiography in control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private outpatient Radiology Clinic

Full name of responsible person
Dr Fatemeh Safi
Street address
Shariati squre,Arak
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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
Dr Mohammad Rafiee
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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

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Full name of responsible person
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Person responsible for scientific inquiries

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Person responsible for updating data

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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