

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Pain perception and side effects during sonohysterography with balloon catheters: a randomized comparative study of cervical with uterine catheter placement

Protocol summary

Summary

Saline infusion sonohysterography and other intrauterine investigations methods may cause uterine cramping, pain and vasovagal reactions. The purpose of this single blind control trial study was to assess whether the location of the balloon catheter either the uterus or cervix during sonohysterography could affect the magnitude of pain and the rate of vasovagal reaction. The proposal of study approved by our institutional review boards and institution's ethical committee, and all participants sign a written consent before enter to study. A total of 300 infertile women aged, 18- 45 years, undergoing sonohysterography were randomized to intrauterine or intracervical balloon catheter placement. The examinations were scheduled in the early follicular phase of menstrual cycle after cessation of menstrual flow and before day 10. After introduction of a 2 lumen 6-French balloon catheter, under sonographic guidance, sterile normal saline solution (10-50 mL) was slowly introduced into the cavity until an adequate distention of the uterine cavity was obtained. Three-dimensional ultrasound scanned volumes were recorded. Scanned volumes were evaluated in multiplanar 3D and Multi-slice view mode, with slice interval of 0.5 mm. Visual analogue scales were used to assess the degree of pain experienced. Outcome measures were assessed based on the intent-to-treat principle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309053553N1**
Registration date: **2013-10-30, 1392/08/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-10-30, 1392/08/08

Registrant information

Name

Fatemeh Zafarani

Name of organization / entity

Royan institute

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Iran (Islamic Republic of)

Phone

+98 21 2356 2446

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fzafarani@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2012-04-30, 1391/02/11

Expected recruitment end date

2013-09-30, 1392/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pain perception and side effects during sonohysterography with balloon catheters: a randomized comparative study of cervical with uterine catheter placement

Public title

Optimal catheter placement during sonohysterography

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Infertile patients who are referred to Royan Institute and undergoing sonohysterography for evaluation of the internal structure of uterine cavity (acquired & congenital abnormalities). Exclusion criteria: Symptoms or signs of active pelvic infection, Abnormal uterine bleeding ,Women with cervical stenosis, Women with each lesions which disrupts catheterization such as large myoma, Risk factors for endometrial cancer

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Royan Institute

Street address

P.O.Box:1935-4644 ,Royan Institute, No. 12, Eastern Hafez Avenue, Bani Hashem Street, Resalat Highway

City

Tehran

Postal code

1665659711

Approval date

2011-12-06, 1390/09/15

Ethics committee reference number

K/09/1060

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Pain perception

Timepoint

At the time of the Balloon inflation and deflation

Method of measurement

10-point visual analog pain scale

2

Description

Vasovagal reaction rate (Hypotention, sweating, nausea, vomiting, syncope)

Timepoint

from inflation of balloon catheter till 30 minutes after deflation

Method of measurement

touching of pulse , sphygmomanometer, observation of respiration , Termometer

Secondary outcomes

1

Description

Total time required to perform of sonohysterography

Timepoint

During of sonohysterography

Method of measurement

Recording of total time of sonohysterography

2

Description

Spontaneous catheter expulsion rate

Timepoint

During of sonohysterography

Method of measurement

Re-Catheter placement rate

3

Description

volume of media required to perform procedure

Timepoint

During of sonohysterography

Method of measurement

Measuring of volume of injected media during sonohysterography

Intervention groups

1

Description

Intervention group: In this group after introduction of speculum, balloon catheter was inflated in the uterine cavity. Then under sonographic guidance, sterile normal saline (10-50 mL) was slowly introduced into the cavity. When optimal distention of the uterine cavity was obtained, three-dimensional volume sweep of the sagittal, transverse and coronal planes of the uterus were performed.

Category

Diagnosis

2

Description

Control group: In this group after introduction of speculum, balloon catheter was inflated in the cervical canal. Then under sonographic guidance, sterile normal saline (10-50 mL) was slowly introduced into the cavity. When optimal distention of the uterine cavity was obtained, three-dimensional volume sweep of the sagittal, transverse and coronal planes of the uterus were performed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Fatemeh Zafarani , Midwife, M.Sc. Academic staff of Reproductive Imaging Department

Street address

Department of Reproductive Imaging at Reproductive Biomedicine Research Center, Royan Institute for Reproductive Biomedicine, ACECR, ACECR [P.O.Box: 1935-4644, No.12, Eastern Hafez Avenue, Banihashem Street, Resalat Highway]

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Dr. Ahmad Vosough

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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

Royan Institute

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

Royan institute

Full name of responsible person

Firoozeh Ahmadi

Position

Radiologist- Head of Department of Reproductive Imaging

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Midwife, M.Sc., Scientific staff of Department of Reproductive imaging

Other areas of specialty/work

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Full name of responsible person

Saeed Hesam

Position

Biostatistics , M.Sc.

Other areas of specialty/work

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at Reproductive Epidemiology Research Center,
Royan Institute for Reproductive Biomedicine, ACECR

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