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)
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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-dimenstional volume sweep of the sagital, transverse and cronal 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-dimenstional volume sweep of the sagital, transverse and cronal 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]

City
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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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City
Tehran

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

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

Other areas of specialty/work

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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