

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Efficiency of trans-vaginal ultrasonography versus hysteroscopy in finding intrauterine pathologies in infertile women: a diagnostic clinical trial

Protocol summary

Summary

Objectives: To assess the Efficiency of trans-vaginal ultrasonography versus hysteroscopy in finding intrauterine pathologies in infertile women. Design: a diagnostic clinical trial. Setting and conduct: The eligible infertile women who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) being infertile; (b) more than one year has passed from the infertility; (c) infertility due to the woman's somatic disorders Exclusion criteria: having hormonal dysfunction in infertile woman. Intervention group: Diagnostic trans-vaginal ultrasonography once on the first day and then hysteroscopy once on the second day. Control group: Each patient will be examined with both diagnostic approaches, therefore, each patient will be compared with him/herself. Primary outcome: Assessing the intrauterine pathologies. Secondary outcome: Nothing. Randomization: Not applicable because each patient will be compared with him/herself. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510049014N80**
Registration date: **2015-10-12, 1394/07/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-12, 1394/07/20

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2015-08-21, 1394/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficiency of trans-vaginal ultrasonography versus hysteroscopy in finding intrauterine pathologies in infertile women: a diagnostic clinical trial

Public title

Efficiency of trans-vaginal ultrasonography versus hysteroscopy in finding intrauterine pathologies in infertile women

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: (a) being infertile; (b) more than one

year has passed from the infertility; (c) infertility due to the woman's somatic disorders Exclusion criteria: having hormonal dysfunction in infertile woman.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 44

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

Randomization: Not applicable because each patient will be compared with him/herself. Blinding: Not possible.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-06-20, 1394/03/30

Ethics committee reference number

IR.UMSHA.REC.1394.138

Health conditions studied**1****Description of health condition studied**

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Assessing the intrauterine pathologies

Timepoint

On the first day of study

Method of measurement

ultrasonography and hysteroscopy

Secondary outcomes**1****Description**

Nothing

Timepoint

Nothing

Method of measurement

Nothing

Intervention groups**1****Description**

Diagnostic trans-vaginal ultrasonography once on the first day and then hysteroscopy once on the second day

Category

Diagnosis

2**Description**

Each patient will be examined with both diagnostic approaches, therefore, each patient will be compared with him/herself

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fatemieh Hospital

Full name of responsible person

Dr Firoozeh Zonoori

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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 the Technology, Hamadan
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

Fatemieh Hospital

Full name of responsible person

Dr Firoozeh Zonoori

Position

Resident of Gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Fatemieh Hospital

Full name of responsible person

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Gynecologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

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