

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of diagnostic accuracy "three-dimensional transvaginal sonography ", "three-dimensional transvaginal sonography with saline infusion and laparoscopy Hysteroscopy" in diagnosis of septated and bicornuate uterus uterine.

Protocol summary

Summary

The aim of this study is Comparison of diagnostic accuracy "three-dimensional transvaginal sonography ", "three-dimensional transvaginal sonography with saline infusion and laparoscopy Hysteroscopy" in diagnosis of uterine anomalies. This study is prospective interventional. We enrolled 120 child bearing age women with septated or bicornuate uterus by histerosalpingography and obstetric history of miscarriage or candidate for IVF-ICSI .Three-dimensional transvaginal sonography "and "three-dimensional transvaginal sonography with saline infusion was performed for all patients and regard less of the results of three-dimensional transvaginal sonography "and "three-dimensional transvaginal sonography with saline, laparoscopy Hysteroscopy operation was done for all patients then diagnostic results of uterine anomaly by Three-dimensional transvaginal sonography "and "three-dimensional transvaginal sonography with saline and laparoscopy Hysteroscopy operation was compered and diagnostic accuracy of uterine anomaly by"three-dimensional transvaginal sonography "and "three-dimensional transvaginal sonography with saline infusion" and laparoscopy Hysteroscopy operatin was compered. Inclusion criteria were as follow: 1-Child bearing age women with septated or bicornuate uterus by histerosalpingography; 2- obstetric history of miscarriage or candidate for IVF-ICSI. This patients excluded from study: 1- $18 \leq \text{patient age} \leq 45$; 2-No desire for conception; 3-pregnancy; 4-uterine or cervical malignanc; 5-cervicitis, vaginitis and recent history of PID. Interventions included: Three-dimensional transvaginal sonography "and "three-dimensional transvaginal sonography with saline infusion. Main outcome of study is Comparison of diagnosis of uterine anomaly by three-dimensional transvaginal sonography ,

three-dimensional transvaginal sonography with saline infusion and laparoscopy Hysteroscopy operation. Interventions included: 1-Diagnosis of uterine anomaly by three-dimensional transvaginal sonography 2- Diagnosis of uterine anomaly by three-dimensional transvaginal sonography with saline infusion 3-Diagnosis of uterine anomaly by laparoscopy Hysteroscopy operation 4-BMI 5-Prior history of infertility 6-age 7-prior history of abortion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041733490N1**
Registration date: **2017-07-03, 1396/04/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-03, 1396/04/12

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences, Vice chancellor for research

Expected recruitment start date

2017-05-16, 1396/02/26

Expected recruitment end date

2018-03-17, 1396/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of diagnostic accuracy "three-dimensional transvaginal sonography ", "three-dimensional transvaginal sonography with saline infusion and laparoscopy Hysteroscopy" in diagnosis of septated and bicornuate uterus uterine.

Public title

Diagnostic accuracy "three-dimensional transvaginal sonography "and "three-dimensional transvaginal sonography with saline infusion" in diagnosis of uterine anomalies.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria were as follow: 1-Child bearing age women with septated or bicornuate uterus by histerosalpingography; 2- obstetric history of miscarriage or candidate for IVF-ICSI. Exclusion criteria: 1-18≤patient age≤45; 2-No desire for conception; 3-pregnancy; 4- uterine or cervical malignanc; 5-cervicitis, vaginitis and recent history of PID.

Age

From **18 years** old to **44 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

This study has not control group and diagnostic interventional procedure done in all studied patients.

Secondary Ids

empty

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

Ethics committee's Tehran university of medical sciences

Street address

Buiding (N:1), The Northern Gate of university, Poursina Ave, Ghods Ave, Enghelab St, Tehran, Iran.

City

Tehran

Postal code**Approval date**

2017-05-15, 1396/02/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2304

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

uterine anomaly

ICD-10 code

(O00-O99),

ICD-10 code description

congenital malformations, deformations and chromosomal abnormalities, Congenital malformations of genital organs, Pregnancy with abortive outcome, inborn errors of metabolism, Pregnancy, childbirth and the puerperium

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

the presence of uterine anomaly

Timepoint

One to Three months before laparoscopy Hysteroscopy operation and sameday

Method of measurement

three-dimensional transvaginal sonography and three-dimensional transvaginal sonography with saline infusion and laparoscopy Hysteroscopy

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

Others uterine anomalies

Timepoint

Before and day of laparoscopy Hysteroscopy

Method of measurement

Three-dimensional transvaginal sonography and three-dimensional transvaginal sonography with saline infusion and laparoscopy Hysteroscopy

Intervention groups

1

Description

Three-dimensional transvaginal sonography

Category

Diagnosis

2

Description

Three-dimensional transvaginal sonography with saline infusion

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Mahbod Ebrahimi

Street address

Yas hospital, Fourth alley corner, North Ostad Negatoollahi Avenue, Karimkhan street, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran university of medical sciences, Vice chancellor for research

Full name of responsible person

Mahbod Ebrahimi

Street address

Research Department, Floor (No:6), Central building of university, Around the corner of Ghods Ave, Keshavarz Buld, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran university of medical sciences, Vice chancellor for research

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

Tehran university of medical sciences

Full name of responsible person

Zahra Dehbashi

Position

Graduated student of infertility floship

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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