

# 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

##### Name

Zahra Dehbashi

##### Name of organization / entity

Tehran university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8608 9076

##### Email address

zdehbashi@razi.tums.ac.ir

##### 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

#### Street address

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

#### City

Tehran

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zddoctor1390@gmail.com

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran university of medical sciences

#### Full name of responsible person

Mahbod Ebrahimi

#### Position

Faculty member

#### Other areas of specialty/work

#### Street address

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

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Maeb214@yahoo.com

#### 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*