

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### **A comparative study on some of the consequences of fetal transfer method under the guidance of transvaginal ultrasound and guidance through trans Abdominal ultrasound at Mahdiah Hospital in Tehran in 2020**

#### **Protocol summary**

##### **Study aim**

Comparing the two methods of embryo transfer; under guidance of transvaginal and transabdominal ultrasound.

##### **Design**

The present study is a clinical trial study. 90 women candidates for IVF will enter the study using simple randomly method and will be randomly divided into two groups with equal numbers.

##### **Settings and conduct**

In both groups of patients, vagina will be lubricated with 10 cc of lubricated gel and, depending on the operator's discretion, two SIVF catheter or Edwards-Wallace catheters will be used. To perform sonography, a Honda device made in China with H-S2000 probe will be used for abdominal ultrasound and H-S2100 probe will be used for vaginal ultrasound. Patient pain will be recorded in checklists during and after the procedure. After the study, the doctor will be asked how difficult it is to perform the procedure and the three-dimensional vision in the two methods studied, and it will be recorded in the questionnaire. Also, the process time will be recorded by a stopwatch.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: According to the normal range of Anti-Müllerian hormone (AMH), the patients with AMH > 0.7 were included. Also, women between ages of 18 and 40, candidate for the embryo transfer. Exclusion criteria: Antral follicle count (AFC) and AMH were always used together to determine ovary response and so patients with poor responses were excluded. Also, obesity (BMI above 35), anatomical problems of uterus, and patients' dissatisfaction to participate in study.

##### **Intervention groups**

First group: transvaginal ultrasound. Second group: transabdominal ultrasound.

##### **Main outcome variables**

Pain rate, Ultrasound imaging of physician, Duration of procedure, Successful pregnancy

#### **General information**

##### **Reason for update**

We requested an update because a few words in the text of the clinical trial differed from the extracted article

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20200115046140N1**

Registration date: **2020-08-09, 1399/05/19**

Registration timing: **retrospective**

Last update: **2022-01-22, 1400/11/02**

Update count: **2**

##### **Registration date**

2020-08-09, 1399/05/19

##### **Registrant information**

###### **Name**

Parya Geran Malekkheyli

###### **Name of organization / entity**

###### **Country**

Iran (Islamic Republic of)

###### **Phone**

+98 21 2990 2233

###### **Email address**

navid.khoshbakht@gmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2020-05-21, 1399/03/01

##### **Expected recruitment end date**

2020-05-30, 1399/03/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparative study on some of the consequences of fetal transfer method under the guidance of transvaginal ultrasound and guidance through trans Abdominal ultrasound at Mahdieh Hospital in Tehran in 2020

**Public title**

comparison of the consequences of fetal transfer method under the guidance of transvaginal ultrasound and guidance through trans Abdominal ultrasound

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Women candidates for IVF Patients with antimullerian hormone more than 0.7 Women between 18 and 40 years old

**Exclusion criteria:**

The patient's reluctance to participate in the study  
Patients with a poor ovarian response (in terms of number of antral follicles and antimullerian hormone)  
Obesity (BMI above 35) Uterus anatomical problems

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, 90 women candidates for IVF will be included in the study by simple randomly method. Using simple randomization method and individual unit, division of people into two groups will be done by Research Randomizer software, version 3.0 and random allocation with a ratio of 1: 1. In this software, a number will be assigned to each person entered in the study, and the software will randomly separate the numbers in two lists with a ratio of 1: 1.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

**Street address**

Tehran - Shahid Chamran Highway - Yemen Street - Next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2019-01-06, 1397/10/16

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1397.870

**Health conditions studied**

**1**

**Description of health condition studied**

IVF

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Pain severity

**Timepoint**

During the ultrasound, At the end of the ultrasound

**Method of measurement**

Number one as the least pain and number ten as the most pain. Measuring of the variable will be done using the Numeric Pain Rating Scale method. In this method, the person rates their pain using a scale of 0 to 10. Zero means painless and 10 means the worst pain situation.

**2**

**Description**

Ultrasonic visualization of the doctor

**Timepoint**

At the end of the ultrasound

**Method of measurement**

Appropriate / inappropriate. This variable will be done by asking the doctor at the end of the ultrasound. In this way, the degree of difficulty and three-dimensional vision of the doctor using this method will be recorded based

on the physician's opinion.

### 3

#### **Description**

Processing time

#### **Timepoint**

At the end of the ultrasound

#### **Method of measurement**

Second. The duration of the ultrasound at the end of the work will be recorded using a stopwatch in according to seconds.

### 4

#### **Description**

Successful pregnancy

#### **Timepoint**

It will be done 4 weeks after embryo transfer.

#### **Method of measurement**

Yes/No. Successful pregnancy will be recorded using beta-HCG measurement.

### 5

#### **Description**

Frequency of tenaculum

#### **Timepoint**

At the end of the ultrasound

#### **Method of measurement**

It was used or not. Using or not of tenaculum will be reported at the end of sonography.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: transfer of the fetus to the uterus under the guidance of abdominal ultrasound. In this group, embryo transfer will take place on days 2 or 3, because pregnancy and the rate of implantation are higher on these days. Initially, the vaginal will be impregnated with 10 cc of lubricating gel, and two SIVF catheters or Edwards-Wallace catheters will be used, depending on the operator's discretion. A rigid external transmission catheter in the cervical canal will also be studied. In this group, the bladder should be full. Honda device made in China with H-S2000 probe will be used for ultrasound.

#### **Category**

Treatment - Devices

### 2

#### **Description**

Intervention group: transfer of the fetus to the uterus under the guidance of vaginal ultrasound. In this group, embryo transfer will take place on days 2 or 3, because

pregnancy and the rate of implantation are higher on these days. Initially, the vagina will be impregnated with 10 cc of lubricating gel, and two SIVF catheters or Edwards-Wallace catheters will be used, depending on the operator's discretion. A rigid external transmission catheter in the cervical canal will also be studied. Honda device made in China with H-S2100 probe will be used for ultrasound.

#### **Category**

Treatment - Devices

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Tehran Mahdiyeh Hospital

##### **Full name of responsible person**

Parya Geran Malekkheyli

##### **Street address**

Tehran - Shahid Chamran Highway - Yemen Street -  
Next to Taleghani Hospital - Shahid Beheshti  
University of Medical Sciences

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##### **Province**

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##### **Postal code**

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##### **Email**

navid.khoshbakht@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Parya Geran Malekkheyli

##### **Street address**

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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**  
Shahid Beheshti University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Parya Geran Malekheyli  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Position**  
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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
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**Latest degree**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

\*

### When the data will become available and for how long

\*

**To whom data/document is available**

\*

**Under which criteria data/document could be used**

\*

**From where data/document is obtainable**

\*

**What processes are involved for a request to access data/document**

\*

**Comments**