Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Mahdieh 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
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9770
Fax
+98 21 2243 9770
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
Tehran - Shahid Chamran Highway - Yemen Street - Next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2243 9770
Fax
+98 21 2243 9770
Email
navid.khoshbakht@gmail.com

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 Malekkheyli
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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
Phone
+98 21 2243 9770
Email
navid.khoshbakht@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parya Geran Malekkheyli
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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
Phone
+98 21 2243 9770
Email
navid.khoshbakht@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parya Geran Malekkheyli
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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
Phone
+98 21 2243 9770
Email
navid.khoshbakht@gmail.com

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