

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison the pregnancy outcomes in patients with adenomyosis after pitutary down-regulation with GnRHagonist plus hormone replacement therapy versus HRT for endometrial preparation in frozen embryo transfer cycles

Protocol summary

Study aim

Comparison of two endometrial preparation protocols for frozen-thawed embryo transfer in patient with adenomyosis

Design

This study is designed as a randomized, single-blind clinical trial with parallel groups with a sample size of 65 individuals per group

Settings and conduct

This study will be done on 130 women with adenomyosis undergoing frozen embryo transfer. After random allocation, they will be treated with GnRH+HRT or HRT. Pregnancy outcomes will be assessed in both groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 30-45 Years First or second cycle of embryo transfer, Normal uterine cavity adenomyosis with or without endometriosis and myoma. Exclusion criteria: recurrent implantation failure, hydrosalpinx, uterine anomaly, severe male factor infertility myoma >5 cm severe endometriosis uterine distortion because of myoma

Intervention groups

Intervention group1: endometrial preparation with HRT+GnRHa Intervention group2: endometrial preparation with HRT

Main outcome variables

chemical pregnancy and clinical pregnancy and ongoing pregnancy.

General information

Reason for update

Due to the fact that the rate of chemical pregnancy, the rate of miscarriage, and the rate of twins pregnancy have also been investigated and followed up, therefore, they were added in the primary and secondary results

section.

Acronym

IRCT registration information

IRCT registration number: **IRCT20090526001952N13**

Registration date: **2020-12-24, 1399/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-03, 1401/10/13**

Update count: **4**

Registration date

2020-12-24, 1399/10/04

Registrant information

Name

Ashraf Moini

Name of organization / entity

Tehran University of Medical sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the pregnancy outcomes in patients with adenomyosis after pitutary down-regulation with GnRHagonist plus hormone replacement therapy versus HRT for endometrial preparation in frozen embryo transfer cycles

Public title

Comparison of two endometrial preparation protocols for frozen-thawed embryo transfer in patient with adenomyosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 30-45 Years First or second cycle of embryo transfer
Presence of adenomyosis, either focal or generalized, with or without concomitant diagnosis of endometriosis and myoma Normal uterine cavity

Exclusion criteria:

recurrent implantation failure, hydrosalpinx, uterine anomaly , sever male factor infertility myoma >5 cm
sever endometriosis uterine distortion because of myoma

Age

From **30 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 140 people, with 70 people in each group. The Block randomization method was designed by the epidemiologist using STATA version . 13 software. The kind of treatment will put in the pocket. When the doctor confirmed the eligibility of the patient the midwife will give the pocket to the doctor.

Blinding (investigator's opinion)

Single blinded

Blinding description

Because of the kind of intervention, The patient will be aware of the treatment. Outcomes assessor will not be informed about the kind of treatment A statistician who is unaware of the type of interventions in each group will analyze the data

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Baghdarnia St.

City

Tehran

Province

Tehran

Postal code

1653915981

Approval date

2020-04-30, 1399/02/11

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.034

Health conditions studied

1

Description of health condition studied

Infertility in adenomyosis

ICD-10 code

N97.2

ICD-10 code description

Female infertility of uterine origin

Primary outcomes

1

Description

Clinical pregnancy rate

Timepoint

Observation of at least one fetus with cardiac activity at 4-6 weeks after embryo transfer in vaginal ultrasound

Method of measurement

Vaginal ultrasound

2

Description

Chemical pregnancy rate

Timepoint

14 days after embryos transfer

Method of measurement

by using laboratory kits for blood Beta-hCG assay

Secondary outcomes

1

Description

Live birth rate

Timepoint

The delivery of a fetus who shows evidence of life after that is entirely outside of the mother

Method of measurement

Delivery report from hospital

2

Description

Miscarriage rate

Timepoint

Before the 20th week of pregnancy

Method of measurement

Ultrasound evidence of clinical pregnancy loss before 20 weeks of gestation

3

Description

Twin pregnancy rate

Timepoint

6 to 7 weeks after embryo transfer

Method of measurement

observation of two gestational sacs along with the fetal poles with heart beat in ultrasound examination

Intervention groups

1

Description

Control group: This group will received dipherelin (3.75 mg) On day 3 after LMP, and then repeat after 28 days .7-14 days after second dose then estradiol valerate is administered at the dose of 2 mg and will be increased to 6 mg /daily. The patient will be examined after 10-14 days. An endometrial thickness of 8 mm or more is optimum for progesterone administration ,(an injectable progesteron 100 mg /daily) otherwise the dose of estradiol will be increased up to 8 mg. If the optimal endometrial thickness is not achieved after 20 days, embryo transfer will be canceled.

Category

Treatment - Drugs

2

Description

Intervention group: This group will be received estradiol valerate (Aboureiha Co.). On day2 after LMP, estradiol valerate is administered at the dose of 2 mg and will be increased up to 6 mg. The patient will be examined after 10-14 days. An endometrial thickness of 8 mm or more is optimum for progesterone administration (injectable progesteron 100 mg/daily), otherwise the dose of estradiol will be increased up to 8 mg. If the optimal endometrial thickness is not achieved after 20 days, embryo transfer will be canceled.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women Hospital

Full name of responsible person

dr marzieh eslami moayed

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeian

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

dr marzieh eslami moayed

Position

professor assistant

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available