

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of growth hormone intrauterine injection along oral hormone replacement on refractory thin endometrium in frozen embryo transfer cycles

Protocol summary

Study aim

Investigating the effect of growth hormone intrauterine injection along oral hormone replacement on refractory thin endometrium in frozen embryo transfer cycle

Design

Before-after clinical trial on 25 patients with refractory thin endometrium

Settings and conduct

It is a before-after intervention study that will be carry out in Al-Zahra univercity hospital. every other day injection of 5 units intrauterine growth hormone, under the guide of abdominal ultrasound with a special catheter of IUI, until the thickness of the endometrium exceeds 7 mm, maximum 5 times.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Women aged 19-45 years with thin endometrium, less than 7 mm, and history of cancellation of fetal transfer cycle during hormone transfer therapy cycle 2. Normal hysteroscopy during the last 6 months 3. Informed consent Exclusion criteria: 1. Diabetics 2. History of any cancer 3. Cardiovascular Disease 4. Prohibition of pregnancy 5. Adenomyosis and uterine fibroids 6. Women who are contraindicated in using estrogen for any reason, such as a history of thrombosis, liver disease, dyslipidemia

Intervention groups

25 infertile women aged 19-45 years with a history of cancellation of the embryo transfer cycle due to thin endometrium during the previous frozen embryo transfer hormone therapy cycle are included in this study

Main outcome variables

1. Increasing endometrial thickness 2. Biochemical pregnancy 3. Clinical pregnancy 4. Ongoing pregnancy: pregnancy over 12 weeks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210220050429N1**

Registration date: **2021-04-13, 1400/01/24**

Registration timing: **prospective**

Last update: **2021-04-13, 1400/01/24**

Update count: **0**

Registration date

2021-04-13, 1400/01/24

Registrant information

Name

Soghra Hosseini aghdam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 1622

Email address

dr.s.aghdam@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of growth hormone intrauterine injection along oral hormone replacement on refractory thin endometrium in frozen embryo transfer cycles

Public title

Effect of growth hormone in the treatment of infertility

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

25 infertile women aged 19-45 years with a history of endometrial thickness less than 7 mm on the last day of endometrial preparation with estrogen in the previous cycle of embryo transfer.

Exclusion criteria:

Age over 45 years, Diabetic patients, History of cancer, Cardiovascular disease, Any disease that threatens the mother's life and prohibits pregnancy and fetal transfer, Uterus with adenomyosis and uterine fibroids, History of thrombosis, liver disease, Dyslipidemia

Age

From **19 years** old to **45 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz Medicine University

Street address

Baghshomal Ave, Alzahra Hospital, Tabriz city, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-02-08, 1399/11/20

Ethics committee reference number

IR.TBZMED.REC.1399.1039

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

Women infertility

ICD-10 code

N97

ICD-10 code description

Women infertility

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

Chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

Check of serum BHCG

2**Description**

Clinical pregnancy

Timepoint

4weeks after embryo transfer

Method of measurement

Seeing intra uterine gestational sac in vaginal sonography

3**Description**

Ongoing pregnancy

Timepoint

10 weeks after embryo transfer

Method of measurement

Sonography and see the heart beat of embryo

4**Description**

Increase in endometrial thickness after intrauterine infusion of growth hormone

Timepoint

Measurement endometrial thickness at the beginning and at the end day of intrauterine growth hormone injection

Method of measurement

Trans sagittal vaginal sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this prospective after-before interventional study, 25 patients aged 19-45 years with a history of endometrial thickness less than 7 mm in the estrogen therapy cycle of frozen embryo transfer are studied to evaluate the effect of intrauterine growth hormone injection on increasing endometrial thickness. These people underwent vaginal ultrasound on the second day of the menstrual cycle and if no dominant follicle is seen, the necessary treatment for endometrial preparation with oral estradiol valerate tablets, 2 mg tablets of Abu Reihan Company, Tehran, Iran, at a dose of 2 mg three times a day, It starts for 7 days, then the second ultrasound is performed and the thickness of the endometrium is measured in the longest part of the longitudinal section. If the thickness of the endometrium is less than 7 mm, the dose of the drug is 8 mg, 2 mg 4 times a day, for four days. A few days after taking a high dose of the drug, the thickness of the endometrium in the longitudinal section of the uterus is measured twice. On day 12-14 of the cycle, if the thickness of the endometrium is less than 7 mm, a slow intrauterine injection every other day, 5 units of growth hormone ,Sinatropin drug form from Sinagen Company, Basu Rat 5 ml in 1.5 cc containing 15 units of growth hormone and diluted with 0.3 ml of normal saline 0.9% percent and 0.6 cc of this solution contains 5 units of growth hormone, under the guide of abdominal ultrasound with a special catheter, Labutek-Germany, is performed until the endometrial thickness reaches or equal to 7 mm, maximum 4-5 times. If the thickness does not increase, the cycle is canceled and if the thickness increases to 7 mm and above, two days later serum estradiol level is measured. Progesterone ampoules are injected 100 mg daily for 3-5 days depending on the type of embryo transferred. Progesterone ampoules are continued for up to 12 weeks in case of pregnancy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Alieh Gasemzade

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Soghra Hosseini Aghdam

Position

Infertility Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There are no more information

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

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

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

article

When the data will become available and for how long

2021

To whom data/document is available

all ones

Under which criteria data/document could be used

citation- practice

From where data/document is obtainable

web site of journal

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

search in web site of journal

Comments