Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Tabriz University of Medical Sciences

Full name of responsible person

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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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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Professor
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Person responsible for updating data

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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