

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Growth Hormone on Improve Pregnancy Rate in Women with poor ovarian response

Protocol summary

Study aim

Determining the effect of growth hormone on increasing the rate of successful pregnancy in patients with poor ovarian response

Design

Single-blind randomized double-arm clinical trial study in two groups of growth hormone and no-growth hormone receiving patients with poor ovarian response

Settings and conduct

In this prospective study by clinical trial method, patients with poor ovarian response as Blocked Randomization are divided in two groups, receiving 4 units of growth hormone subcutaneous daily from 21st day of menstruation before starting the cycle to the day of trigger injection and control group without receiving growth hormones. Single blinding is done for researchers conducting the study. Data collection authorities and those evaluating the outcome do not have access to patients' files or patients' clinical report forms.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age less than 40 years, Normal karyotype, Normal thrombophilia (having two or less than two positive tests for thrombophilic heterozygotes), Formation of 5 embryos (more than 3 embryos with good quality). Exclusion criteria: Endometriosis disease, Severe oligospermia (morphology count <1%), Patients with hydrosalpinx

Intervention groups

The intervention group includes patients with poor ovarian response who receive growth hormone intervention. The control group includes patients with poor ovarian response who do not receive growth hormone intervention.

Main outcome variables

Clinical pregnancy by defining the observation of pregnancy sac on transvaginal ultrasound in the 5th week of pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201003048912N2**

Registration date: **2021-02-20, 1399/12/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-20, 1399/12/02**

Update count: **0**

Registration date

2021-02-20, 1399/12/02

Registrant information

Name

Mina Ataei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2020

Email address

m.ataee@abz.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Growth Hormone on Improve Pregnancy Rate in Women with poor ovarian response		aware of the type of assignment of participants to the control and intervention group	
Public title	Effect of Growth Hormone on Improve Pregnancy Rate in Women with poor ovarian response	Placebo	Not used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: Age less than 40 years, Normal karyotype, Normal thrombophilia (having two or less than two positive tests for thrombophilic heterozygotes) Formation of 5 embryos (more than 3 embryos with good quality) Patients with poor ovarian response (history of an ovulation stimulation cycle with less than 4 oocytes and AMH <1.1 and FSH <20) in infertile women referred to Ibn Sina Infertility Treatment Center Exclusion criteria: Endometriosis disease Severe oligospermia (morphology count <1%) Patients with hydrosalpinx History of ovarian surgery Underlying disease such as kidney and liver and diabetes and thyroid autoimmune Allergic local reactions and benign increase in intracranial pressure	Other design features	
Age	From 20 years old to 40 years old	Secondary Ids	empty
Gender	Female	Ethics committees	
Phase	3	1	
Groups that have been masked	Outcome assessor	Ethics committee	
Sample size	Target sample size: 124	Name of ethics committee	University Jihad Avicenna Infertility Center
Randomization (investigator's opinion)	Randomized	Street address	Tehran, Shariati St., corner of Yakhchal St., No. 97, Jihad University Avicenna Infertility Center
Randomization description	The sampling method was convenient and the samples were randomly assigned to two groups of received Growth Hormone counseling (intervention) and non-received Growth Hormone counseling (control) by four-sized randomized blocks. There were six possibilities for inclusion in blocks (BABA, BBAA, ABBA, AAB, ABAB and BAAB). At the beginning of study, one of blocks was selected and four participants were put in that block, so that the number A belonged to the intervention group (GH), and number B to the control group (Non GH). The details of blocks were contained in asset of sealed envelopes; the person that did allocation did not have any information about research. random numbers form with the help of computers. If the number is between 1 and 6.1, block 1. If it is between 6.2 and 12, block 2 and continue this way up to 30.1-36.2 to be in block 6.	City	Tehran
Blinding (investigator's opinion)	Single blinded	Province	Tehran
Blinding description	The researchers responsible for data collection and those who assess outcomes will not have access to patients' medical records and clinical report forms. They will simply collect patients' outcomes based on the initial list for participation in the research. These people will not be	Postal code	1941913114
		Approval date	2020-10-06, 1399/07/15
		Ethics committee reference number	IR.ACECR.AVICENNA.REC.1399.018
		Health conditions studied	
		1	
		Description of health condition studied	Patients with poor ovarian response
		ICD-10 code	N97
		ICD-10 code description	Female infertility
		Primary outcomes	
		1	
		Description	Pregnancy rate
		Timepoint	Three months after taking the drug
		Method of measurement	The number of patients with BHCG positive is divided by the number of patients who had fetus transfer
		Secondary outcomes	empty

Intervention groups

1

Description

Intervention group: Patients will receive 4 units of subcutaneous growth hormone of Sinagen Company from the 21st day of menstruation, one month before the start of cycle to the day of trigger hug injection. From the third day of menstruation, the patient will receive a gonadotropin injection and an antagonist protocol according to the routine of Ibn Sina Infertility Center, and it continues until the day of the growth hormone trigger injection; 36 hours after trigger injection, they will be punctured and according to endometrial conditions, they will routinely be undergone frozen or fresh embryo transfer.

Category

Other

2

Description

Control group: Patients without receiving growth hormone from the third day of menstruation receive gonadotropin injection and antagonist protocol according to the routine of Ibn Sina Infertility Center and it continues until the day of growth hormone trigger injection; 36 hours after trigger injection, they are punctured and according to endometrial conditions, they are routinely undergone to frozen or fresh embryo transfer.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Jihad University Research Institute, Avicenna Infertility Center

Full name of responsible person

Soheila Ansaripour

Street address

Shariati St., corner of Yakhchal St., No. 97, Jihad University , Avicenna Infertility Center

City

Tehran

Province

Tehran

Postal code

1941913118

Phone

+98 21 2243 2020

Fax

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Email

soh.ansaripour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Avicenna University Jihad Infertility Center Avicenna

Full name of responsible person

Dr. Mina Ataei

Street address

Marzdaran Town, Isar St., Motamedi St., Sahel Alley, No. 2

City

Tehran

Province

Tehran

Postal code

1941913114

Phone

+98 21 2243 2020

Fax

+98 21 2243 2020

Email

Atlee.mina@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Avicenna University Jihad Infertility Center Avicenna

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Avicenna University Jihad Infertility Center

Full name of responsible person

Dr. Mina Ataei

Position

Infertility Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Marzdaran Town, Isar St., Motamedi St., Sahel Alley, No. 2

City

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Province

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Avicenna University Jihad Infertility Center
Full name of responsible person
Dr. Mina Ataei
Position
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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Position
Infertility Fellowship
Latest degree
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Other areas of specialty/work
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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

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Effect of Growth Hormone on Improve Pregnancy Rate in Women with poor ovarian response

When the data will become available and for how long

Up to one year after the publication of the article

To whom data/document is available

Access to the effect of chemical and clinical pregnancy rates after receiving growth hormone will be available to other researchers and physicians in coordination with the principal investigator.

Under which criteria data/document could be used

Using in meta-analysis studies

From where data/document is obtainable

Marzadaran Town, Isar St., Motamedi St., Sahel Alley, No. 2 Avicenna University Jihad Infertility Center Dr. Mina Ataei Tell: 00982122432020

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

Email to corresponding author Dr Mina Ataei
Ataee.mina@yahoo.com

Comments