

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the relationship between mid-cycle progesterone level and success rate in IUI(Intrauterine sperm injection) cycles

Protocol summary

Study aim

Investigating the relationship between midcycle progesterone level and success rate in IUI(Intrauterine sperm injection) cycles

Design

The study will be conducted on 200 women aged 18 to 35 with primary or secondary infertility who are candidates for IUI (Intrauterine sperm injection) Patients will be do not randomized

Settings and conduct

This study will be carried out at al-Zahra hospital in Tabriz. 200 women aged 18 to 35 with primary or secondary infertility who are candidates for IUI(Intrauterine sperm injection) will be included in the study.From the third day of the cycle, two tablets of clomfenin or letrozole are given daily for 5 days, and on days 6, 8 and 10, one gonadotropin is given and vaginal sonography is given 5 days after the end of the pill. If there is at least one dominant follicle Above 18 mm) HCG(Human gonadotropin hormone) and measured the serum LH(Luteinizing Hormone) and progesterone levels the same day before administration of HCG. 36 hours after HCG injection, IUI is performed and 14 days after IUI pregnancy test is performed and HCG blood is measured. If HCG is positive, 2 weeks later ultrasound is performed from pregnant patients. Pregnancy rates are compared at different levels of serum progesterone.

Participants/Inclusion and exclusion criteria

Infertile women aged 18 to 35 years and in case of hyperprolactinemia, thyroid disorders, endometriosis, and severe male factor do not enter the study.

Intervention groups

From the third day of the cycle, two tablets of clomfenin or letrozole are given daily for 5 days, and on days 6, 8 and 10, one gonadotropin is given and vaginal sonography is given 5 days after the end of the pill. If there is at least one dominant follicle Above 18 mm) HCG(Human gonadotropin hormone) and measured the serum LH(Luteinizing Hormone) and progesterone levels

the same day before administration of HCG. 36 hours after HCG injection, IUI is performed and 14 days after IUI pregnancy test is performed and HCG blood is measured. If HCG is positive, 2 weeks later ultrasound is performed from pregnant patients. Pregnancy rates are compared at different levels of serum progesterone.

Main outcome variables

Progesterone level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110301005942N5**

Registration date: **2018-01-17, 1396/10/27**

Registration timing: **prospective**

Last update: **2018-01-17, 1396/10/27**

Update count: **0**

Registration date

2018-01-17, 1396/10/27

Registrant information

Name

Aliye Ghasemzadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3553 9160

Email address

gasemzadeha@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-20, 1396/10/30
Expected recruitment end date
2019-02-19, 1397/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the relationship between mid-cycle progesterone level and success rate in IUI(Intrauterine sperm injection) cycles

Public title
Investigating the relationship between mid-cycle progesterone level and success rate in IUI(Intrauterine sperm injection) cycles.

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Women with primary or secondary infertility Age between 18 and 35 years

Exclusion criteria:

Hyperprolactinemia Thyroid disorders Endometriosis sever mal factor

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **200**

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 University Of Medical Sciences

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2017-11-16, 1396/08/25

Ethics committee reference number

IR.TBZMED.REC.1395.701

Health conditions studied

1

Description of health condition studied

Female Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Reducing the cost of infertility treatment with regard to the ability to determine the success rate in that cycle

Timepoint

14 days after IUI

Method of measurement

Blood HCG test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: From the third day of the cycle, two tablets of clomfenin or letrozole are given daily for 5 days, and on days 6, 8 and 10, one gonadotropin is given and vaginal sonography is given 5 days after the end of the pill. If there is at least one dominant follicle Above 18 mm) HCG(Human gonadotropin hormone) and measured the serum LH(Luteinizing Hormone) and progesterone levels the same day before administration of HCG. 36 hours after HCG injection, IUI(Intrauterine sperm injection) is performed and 14 days after IUI pregnancy test is performed and HCG blood is measured. If HCG is positive, 2 weeks later ultrasound is performed from pregnant patients. Pregnancy rates are compared at different levels of serum progesterone performed from pregnant patients. Pregnancy rates are compared at different levels of serum progesterone.

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital
Full name of responsible person
Aliyeh Ghasemzadeh
Street address
Alzahra Hospital, South Artesh St.
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Tabriz
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5138665793
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+98 41 3553 9161
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lahroudin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research,Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Alireza Rashidi
Street address
Third Floor, Central Building of Number2, Golgasht Street
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Tabriz
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5138665793
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+98 41 3553 9161
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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

Vice chancellor for Research,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
Aliyeh Ghasemzadeh
Position
Professor of Obstetrics and Gynecology
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Aliyeh Ghasemzadeh

Position

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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