Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of adding letrozole to gonadotropin on pregnancy outcomes in patients who are the candidate for assisted reproductive techniques

Protocol summary

Study aim
Effect of adding letrozole to gonadotropin on pregnancy outcomes

Design
Clinical trials, sample size 100 patients, phase 3 of the clinical trial, with the control group, with parallel groups, without blindness, randomized with an enveloped packet.

Settings and conduct
This Randomized clinical trial without blindness is conducted for evaluating the effect of intrauterine injection of PRP in Asherman patients referred to Shahid Sadoughi Hospital or Research and Clinical Center for Infertility, Yazd, Iran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Infertile patients which are the candidate for ART. Exclusion criteria: History of endocrine disorders, Intrauterine abnormality (uterine polyp & submucosal fibroma & intrauterine adhesions), Azoospermia of partner Severe endometriosis

Intervention groups
Intervention group: since the second day of the cycle all patients Will receive 150 unit gonadotropin, all patients in this group will receive 5 mg letrozole orally science the second day of the cycle When dominant follicle reached to 12-13 mm, antagonist.25 mg will be injected daily subcutaneously. when dominant follicle reaches 17 mm, final triggering will be done. Control group: since the second day of the cycle all patients Will receive 150 unit gonadotropin, When the dominant follicle reached 12-13 mm, antagonist.25 mg will be injected daily subcutaneously. when dominant follicle reaches 17 mm, final triggering will be done.

Main outcome variables
Chemical pregnancy rate, clinical pregnancy rate

General information

Reason for update
Updating the trial according to the last changes in methods and adding results

Acronym

IRCT registration information
IRCT registration number: **IRCT20110509006420N19**
Registration date: **2018-09-18, 1397/06/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-31, 1400/01/11**
Update count: **2**

Registration date
2018-09-18, 1397/06/27

Registrant information

Name
Maryam Eftekhar

Name of organization / entity
Yazd Research and Clinical Center for Infertility

Country
Iran (Islamic Republic of)

Phone
+98 35182470856

Email address
eftekhar@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-01, 1397/05/10

Expected recruitment end date
2019-02-01, 1397/11/12

Actual recruitment start date
2018-08-01, 1397/05/10

Actual recruitment end date
2018-12-30, 1397/10/09

Trial completion date
2019-02-15, 1397/11/26

Scientific title

The effect of adding letrozole to gonadotropin on pregnancy outcomes in patients who are the candidate for assisted reproductive techniques

Public title
Letrozole in assisted reproductive techniques protocol
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to the Infertility Center, which is undergoing ovulation induction for assisted reproductive techniques. normal ovarian reserve
Exclusion criteria:
History of endocrine disorders Intrauterine abnormality (uterine polyp & sub mucosal fibroma & intrauterine adhesions) Azoospermia of partner Severe endometriosis
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Using computer-generated random numbers in wrapped, unlabeled envelope each holding a unique number.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic commitee of Yazd research center for infertility-Shahid Sadoughi University of Medical Scienc
Street address
Bouali
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2018-06-20, 1397/03/30
Ethics committee reference number
Ir.SSU.RSI.REC.1397.009

Health conditions studied

1

Description of health condition studied
female Infertility
ICD-10 code
N97.9
ICD-10 code description
Female infertility, unspecified

Primary outcomes

1

Description
Chemical pregnancy
Timepoint
15 days after embryo transfer
Method of measurement
Blood laboratory kit

2

Description
Clinical pregnancy
Timepoint
3 weeks after positive beta-h Cg
Method of measurement
Observation of fetal heart activity by transvaginal ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Antagonist group: since the second day of the cycle all patients Will receive 150 unit of cinal f(cinagen-Iran) Subcutaneously When dominant follicle reached to 12-13 mm, cetrotide (Merck- Serono Germany).25 mg will be injected daily subcutaneously. when dominant follicle reaches to 17 mm, final triggering will be done by HCG (Pregnyl - Germany) intramuscular and .2cc decapeptide(Ferring, Germany) Subcutaneously and 36 hours later oocytes pick up will be done.
Category
Treatment - Drugs

2

Description

Intervention group: antagonist group: since the second day of the cycle all patients Will receive 150 unit of cinal f(cinagen-Iran) Subcutaneously, all patients in this group will receive 5 mg letrozole (Iran hormone-Iran)) orally science send day of cycle, When dominant follicle reached to 12-13 mm, cetrotide (Merck- Serono Germany).25 mg will be injected daily subcutaneously. when dominant follicle reaches to 17 mm, final triggering will be done by HCG (Pregnyl - Germany) intramuscular and .2cc decapeptide(Ferring, Germany) Subcutaneously and 36 hours later oocytes pick up will be done.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd Reaserch and clinical for infertility
Full name of responsible person
Abbas aflatoonian
Street address
Bouali
City
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Province
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Postal code
8916877391
Phone
+98 35 3824 7085
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abbas/aflatoonian@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
Street address
Shahid Sadoughi
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Yazd
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Yazd
Postal code
8916978477
Phone
+98 35 3724 0171
Email
masoud_mirzaei@hotmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Maryam Eftekhar
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
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Person responsible for scientific inquiries

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Position
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Latest degree
Medical doctor
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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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City

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Phone

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Email

eftekharmaryam@yahoo.com

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

Due to the privacy of patients

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

Yes - There is a plan to make this available

Title and more details about the data/document

The study protocol, the statistical analysis map, the clinical study report will be available after the publishing of the article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

use in the retrospective study

From where data/document is obtainable

use in the retrospective study

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

Request from the Research Deputy, submitted to the Research Council of the Center if the request accepts its referral to the security and after completion of the relevant forms, the request is referred to the research experts and then get the data.

Comments

Trial results

Please tick if results have been published

Yes

Summary result posting date

2021-03-07, 1399/12/17

Table of baseline comparison

Participant flow diagram

Table of variable outcomes' results

Table of adverse events

First publication date

2020-04-30, 1399/02/11

Abstract of published paper

Abstract Background Aromatase inhibitors prevent the aromatization of androgens into estrogens, which reduces the negative feedback of estrogen on the hypothalamic-pituitary axis. It is clear that increasing the secretion of follicle-stimulating hormones results in an increased follicular growth. Objective This study aimed to evaluate the effect of adding letrozole to gonadotropin on in vitro fertilization outcomes in normal responders. Materials and Methods In this randomized clinical trial, 100 normal responder women candidate for controlled ovarian stimulation were randomly enrolled in two groups (n = 50/each). In the case group letrozole was added to gonadotropin in the antagonist protocol. The control group received the conventional antagonist protocol. The main outcome was clinical and chemical pregnancy; and the second outcomes were the number of mature oocytes, the fertilization rate, estradiol level, and the total dose of gonadotropins. Results Basic clinical and demographic features were comparable between the groups. Estradiol level on the day of human-chorionic-gonadotropin administration and the total gonadotropin consumption were significantly higher in the control group than the case group (p = 0.045). In addition, the number of MII oocytes was higher (but not significantl) in the case group than the control group (p = 0.09). Moreover, the endometrial thickness was

significantly lower in the case group. There were no significant differences in fertilization rate and chemical and clinical pregnancy rates between the two groups. Conclusion Although adding letrozole to gonadotropin in normal responders reduces the total dose of gonadotropin, it does not improve the pregnancy outcomes.