

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

The effect of long term GnRH agonist before frozen embryo transfer in pregnancy outcomes in women with adenomyosis in avecinna infertility center in 2018_2019

Protocol summary

Study aim

Determination of the effect of long term GnRH agonist before frozen embryo transfer in pregnancy outcomes in women with adenomyosis

Design

Clinical trial with control group

Settings and conduct

Avecinna infertility center

Participants/Inclusion and exclusion criteria

Inclusion criteria: having at least 2 criteria in sonography; age between 20 to 40 years old; the candidate for frozen embryo transfer; the embryo has a quality A or blastocyst. exclusion criteria: recurrent miscarriage, azoospermia in male partner, using alternative infertility treatment services (such as donation), uncontrolled underlying diseases such as diabetes, hypertension, kidney dysfunction, lupus, and untreated thyroid dysfunction, abnormal karyotype, anatomical disorder of the uterus (such as Mullerian anomaly, submucosal myoma with compression effect), thrombophilia, candidate of using any immunosuppressive or immunomodulatory drugs and interventions such as endometrial scratch or Platelet-Rich Plasma.

Intervention groups

The intervention group will receive the GnRH agonist for 3 months.

Main outcome variables

Chemical and clinical pregnancy rate

General information

Reason for update

The trial end date was entered and the final volume of the sample was entered.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160717028967N9**

Registration date: **2019-01-01, 1397/10/11**

Registration timing: **prospective**

Last update: **2023-07-27, 1402/05/05**

Update count: **2**

Registration date

2019-01-01, 1397/10/11

Registrant information

Name

Safora Salemi

Name of organization / entity

Shahid Chamran University of Ahvaz

Country

Iran (Islamic Republic of)

Phone

+98 83 3821 1001

Email address

e.mahmoudi@cobeldarou.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-01, 1397/12/10

Expected recruitment end date

2021-02-28, 1399/12/10

Actual recruitment start date

2019-03-01, 1397/12/10

Actual recruitment end date

2021-09-01, 1400/06/10

Trial completion date

2021-09-01, 1400/06/10

Scientific title

The effect of long term GnRH agonist before frozen embryo transfer in pregnancy outcomes in women with

adenomyosis in avecinna infertility center in 2 018_2019

Public title

The effect of long term GnRH agonist before frozen embryo transfer in pregnancy outcomes in women with adenomyosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least 2 criteria in sonography Age between 20 to 40 years old The candidate for frozen embryo transfer The embryo has a quality A or blastocyst

Exclusion criteria:

Recurrent abortion Azospermia in sperm analysis of male partner Uncontrolled medical condition Abnormal karyotype Uterine abnormal anatomy Immune and coagulation dysfunction Using immune suppressive medications Using immune suppressive medications Using another treatments for improvement of fertility success rate

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two equal groups (A and B) based on a randomized six-block table that is designed by Random allocation software.

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

Ethics committee of Avecinna infertility center

Street address

No 97, Yakhchal junction, Shariati street, Avecinna infertility center.

City

Tehran

Province

Tehran

Postal code

1941913114

Approval date

2018-11-20, 1397/08/29

Ethics committee reference number

IR.ACECR.AVICENNA.REC.1397.015

Health conditions studied

1

Description of health condition studied

People with Adenomyosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Pregnancy rate

Timepoint

14 and 16 days after embryo transfer

Method of measurement

Beta test

2

Description

Clinical pregnancy rate

Timepoint

6th week of pregnancy

Method of measurement

With sonography

3

Description

Ongoing pregnancy rate

Timepoint

7th week of pregnancy

Method of measurement

With sonography

4

Description

Abortion rate before 12 weeks

Timepoint

12th week of pregnancy

Method of measurement

With sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The GnRH agonist group treated with a 11.25 mg intramuscular Triptorelin in the 3th menstrual cycle day and after 12 weeks hormone replacement therapy starts with estradiol valerate. Then subjects will be followed with serial transvaginal ultrasound and after reaching to the endometrial thickness of 7 mm, progesterone will be added to the treatment and after 3 to 5 days embryo transfer will be performed.

Category

Treatment - Drugs

2

Description

Control group: In the control group the standard treatment begins with a 21 days of low dose contraceptives from the 3th day of the menstrual cycle and a 1.875 mg intramuscular dose of Triptorelin in the 21th day of menstrual cycle and the hormone replacement therapy starts with estradiol valerate in the next menstrual cycle. Then subjects will be followed with serial transvaginal ultrasound and after reaching to the endometrial thickness of 7 mm, progesterone will be added to the treatment and after 3 to 5 days embryo transfer will be performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Avecinna infertility center

Full name of responsible person

Soheila Ansari pour

Street address

Yakhchal junction, Shariati street, Avecinna infertility center, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1941913114

Phone

+98 21 23519

Email

Soh.ansari pour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Avicenna infertility center

Full name of responsible person

Sharare Shafiei

Street address

No 97, Yakhchal junction, Shariati street, Avicenna infertility center, Tehran, Iran.

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sh.shafiei@yahoo.com

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, Avicenna infertility center

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

Avecinna infertility center

Full name of responsible person

Dr. Soheila Ansari pour

Position

Assistant professor of infertility

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No 97, Yakhchal junction, Shariati street, Avecinna infertility center, Tehran, Iran.

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Postal code

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+98 0982123519

Email

Soh.ansaripour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Avicenna infertility center

Full name of responsible person

Dr. Soheila Ansaripour

Position

Assistant professor of infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Avicenna infertility center

Full name of responsible person

Katayoun Yazdchi

Position

Assistant professor of infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No 97, Yakhchal junction, Shariati street, Avicenna

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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

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

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

Title and more details about the data/document

I have no plans at this time

When the data will become available and for how long

I have no plans at this time

To whom data/document is available

I have no plans at this time

Under which criteria data/document could be used

I have no plans at this time

From where data/document is obtainable

I have no plans at this time

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

I have no plans at this time

Comments