Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

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)

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+98 83 3821 1001

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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 menstural 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 menstural cycle and a 1.875 mg intramuscular dose of Triptorelin in the 21th day of menstural cycle and the hormone replacement therapy starts with estradiol valerate in the next menstural 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 Ansaripour

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

City
Tehran

Province
Tehran

Postal code
1941913114

Phone
+98 21 23519

Email
Soh.ansaripour@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 Ansaripour

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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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
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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