Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the Effect of 17 alpha-hydroxyprogestrone caproate on dcreasing preterm labour and second trimester miscarriage in women pregnant with ART

Protocol summary

Study aim

Evaluation of the effectiveness of 17 alpha-hydroxyprogestrone on decreasing abortion and preterm labor

Design

Women who met inclusion criteria, were informed about the trial design and signed a written consent form. Participants were consecutively enrolled the study and randomly divided into two groups using randomized list. Participants enrolled in a randomized parallel, double-blind, phase 2 clinical trial with control group. Randomization was performed using random number table

Settings and conduct

Women who got pregnant after ART at Yazd Infertility Center and were at 16th week of gestational age were randomly divided into two groups of 7-α hydroxy progesterone and placebo. A double blind trial was performed using placebo (similarity in amount, shape and administration method). patients and data analyzer were blinded to the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women who got pregnant after ART and were at 16 weeks of gestational age. Exclusion criteria: Twin or multiple pregnancies; history of preterm labor; history of previous abortion; history of chronic diseases (Diabetes mellitus, Hypertention, and Hypo or Hyperthyroidism); uterine anatomical problems

Intervention groups

Intervention group: intramuscularly injection of 250 mg17-α hydroxy progesterone from16 to 36 weeks of gestation Control group: intramuscularly injection of 250 mg placebo from16 to 36 weeks of gestation

Main outcome variables

Preterm labor and the second trimester abortion

General information

Reason for update

Updating the trial according to the last changes in inclusion and exclusion criteria, actual number of cases, date of recruitment and trial completion

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101611132N1**
Registration date: **2012-12-24, 1391/10/04**
Registration timing: **retrospective**

Last update: **2022-02-26, 1400/12/07**
Update count: **2**

Registration date

2012-12-24, 1391/10/04

Registrant information

Name

Hoora Amuzegar

Name of organization / entity

Yazd University of Medical Sience

Country

Iran (Islamic Republic of)

Phone

+98 25 1772 2560

Email address

abbas_aflatonian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Ṡhahid Sadoughi University of Medical Siences

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-03-30, 1390/01/10

Actual recruitment start date

2010-10-23, 1389/08/01

Actual recruitment end date

2011-08-30, 1390/06/08

Trial completion date

2011-10-28, 1390/08/06

Scientific title

Evaluation the Effect of 17 alpha-hydroxyprogestrone caproate on dcreasing preterm labour and second trimester miscarriage in women pregnant with ART

Public title

The effect of progestrone on preterm labour in patient who are pregnant with ART teqnique

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnancy using ART Gestational age of 16 weeks Using progesterone for luteal phase support

Exclusion criteria:

Twin or multiple pregnancies History of preterm labor History of previous abortion History of chronic diseases such as Diabetes mellitus, Hypertention, and Hypo or Hyperthyroidism Uterine anatomical problems

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **106**

Actual sample size reached: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

In this trial, 99 women who conceived through ART at 16th weeks of pregnancy were informed about the research design and signed a written consent form. All women were randomly divided into two groups. Randomization was simple, individual using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and statistical analyzer both were blind about the drug or placebo. In placebo group injections were done by a drug similar in shape and volume, but without progesterone which was prepared by the same company as placebo. All injections have done by trained nurses who were blinded about the type of drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadooghi medical university of Yazd

Street address

Central Committee of Medical University, Bahonar sq, Yazd

City

Yazd

Province

Yazd

Postal code

7240171-5

Approval date

2010-10-27, 1389/08/05

Ethics committee reference number

17/1/81633/پ

Health conditions studied

1

Description of health condition studied

preterm labour

ICD-10 code

O60,O75

ICD-10 code description

complication of labour and delivery

Primary outcomes

1

Description

Labour under37week/34-37week-32-34week and second trimestre abortion

Timepoint

weekly from16-36weeks of gestation

Method of measurement

Quastisonaries

2

Description

Etiology of preterm labour

Timepoint

Weekly from16-36weeks of gestations

Method of measurement

Quastionaries

Secondary outcomes

1

Description

NICU admission
Timepoint
After live birth
Method of measurement
Quastionaries

2

Description
Neonatal birth weigh
Timepoint
After live birth
Method of measurement
Quastionaries

3

Description
Drug complication
Timepoint
Weekly from16-36 weeks of gestation
Method of measurement
Quastionaries

Intervention groups

1

Description
control group:drug with all chachtristic of of 17alpha-hydroxyprogestrone caproate:only without efficient material of this drug:intramusculary injected from16-36weeks of gestation
Category
Placebo

2

Description
Drug group:17alpha-hydroxyprogestrone caproate(FEMOLIFE)intramusculary injected from16-36weeks of gestation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Research and Clinical Centre for Infertility of Yazd
Full name of responsible person
Dr. Abbas Aflatonian
Street address
Research and Clinical Centre for Infertility, Bouali Ave, Safaeyeh, Yazd
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Postal code
8916877391
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+98 35 3824 7085
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abbas_aflatoonian@yahoo.com

2

Recruitment center
Name of recruitment center
Madar hospital
Full name of responsible person
Hoora Amuzegar
Street address
Yazd,Mhdieh square,Imam Sadegh Boulevard
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Web page address
http://madarhospital.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Aburaihan Pharmacy company
Full name of responsible person
Aburaihan Pharmacy company
Street address
Tehran,Corner of Tehranpars three way,In front of City hotel.No.1
City
Tehran
Province
Tehran
Postal code
1654613111
Phone
+98 21 7770 7173
Fax
+98 21 7770 2066
Email
info@aburaihan.com
Web page address
http://aburaihan.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Aburaihan Pharmacy company

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Reseach and Clinical Centre for Infertility of Yazd

Full name of responsible person

Dr. Hoora Amuzegar

Position

Resident of Obstetrics and Gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Research and Clinical Centre for Infertility of Yazd

Full name of responsible person

Dr. Abbas Aflatonian

Position

Obstetrics and Gynecologyst and Proffesor of Infertility

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Research and Clinical Centre for Infertility of Yazd

Full name of responsible person

Dr. Hoora Amuzegar

Position

Resident of Obstetrics and Gynecology

Latest degree

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Other areas of specialty/work

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Postal code

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Phone

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Email

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Web page address

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

Yes - There is a plan to make this available

Title and more details about the data/document

All participant data sets are to be shared

When the data will become available and for how long

2 months after the result publication

To whom data/document is available

A journal in which the results are published

Under which criteria data/document could be used

Submission of an official application via the agent that is legally in charge

From where data/document is obtainable

Yazd Reproductive Sciences Institute, Bouali Ave, Yazd, Iran. 983538247085

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

Submission of an official application via the agent that is legally in charge

Comments