

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of oral progesterone(dydrogestron) on incidence of glucose intolerance in pregnant females with threatened abortion

Protocol summary

Summary

Objectives: Spontaneous abortion is the most common pregnancy complications that can had a bad psychological effect on the lives of couples seeking to have a baby. In the early stages Continuation of pregnancy, depends on progesterone production by the corpus luteum. Impaired glucose metabolism during pregnancy is the most important diseases in pregnancy, using oral progesterone to prevent preterm delivery in pregnant women are widely prescribed by gynecologists. We decided to study the effect of oral progesterone (dydrogestron) on incidence of glucose intolerance in pregnant females with threatened abortion. Design & setting & conduct: In this prospective study 50 pregnant women who were tested for blood sugar and had normal blood sugar levels with gestational age less than 14 weeks and complaint threatened abortion, had administration of oral Dydrogesterone 10 mg twice daily to prevent miscarriage and preterm delivery. 50 women who did not use oral dydrogesterone formed the control group. Inclusion criteria: singleton pregnancy, the absence of any systemic disease, age less than 30 years, BMI less than 25, no history of stillbirth, having a family history of diabetes Exclusion criteria: smoking, history of diabetes, gestational diabetes and other systemic diseases, any fetal abnormalities on ultrasound, multiple pregnancy, and previous macrosomia. Interventions: oral administration of dydrogesterone 10 mg twice daily. Outcome: GTT and GCT was checked in14 weeks of gestational age Pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020217035N2**

Registration date: **2016-07-19, 1395/04/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-19, 1395/04/29

Registrant information

Name

Maryam Kasraeian

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 32365

Email address

kasraeem@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral progesterone(dydrogestron) on incidence of glucose intolerance in pregnant females with threatened abortion

Public title

Effect of oral progesterone(dydrogestron) on incidence of glucose intolerance in pregnant females with threatened abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnancy, the absence of any systemic disease, age less than 30 years, BMI less than 25, no history of stillbirth, having a family history of diabetes Exclusion criteria: smoking, history of diabetes, gestational diabetes and other systemic diseases, any fetal abnormalities on ultrasound, multiple pregnancy, previous macrosomia

Age

From **14 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand Avenue

City

Shiraz

Postal code

Approval date

2015-06-10, 1394/03/20

Ethics committee reference number

IR.SUMS.med.REC.1394.25

Health conditions studied

1

Description of health condition studied

Gestational Diabetes

ICD-10 code

Z35

ICD-10 code description

high-risk pregnancy

Primary outcomes

1

Description

FBS

Timepoint

At Gestational age 14 weeks

Method of measurement

Gelocometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: to prevent miscarriage and preterm delivery, had administration of oral Dydrogesterone 10 mg twice daily for intervention group

Category

Treatment - Drugs

2

Description

Control group: the 50 women who did not use oral dydrogesterone formed the control group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Dr Behnaz Karami

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor Of Research, Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Zand Avenue
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor Of Research, Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Behnaz Karami
Position
Student
Other areas of specialty/work
Street address
Zand Avenue
City
Shiraz
Postal code
Phone
+98 71 3612 8257
Fax
Email
drkaramigyneco@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Maryam Kasraeian
Position
Assistant professor
Other areas of specialty/work
Street address
Hafez Hospital
City
Shiraz
Postal code
Phone
+98 71361222220
Fax
Email
maryamkasraeian@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Maternal Fetal Medicine Research Center
Full name of responsible person
Khadije Bazrafshan
Position
Master
Other areas of specialty/work
Street address
City
Postal code
Phone
00
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty