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

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Name of organization / entity
Shiraz University of Medical Sciences
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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 Cmmittee 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

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Position

Student

Other areas of specialty/work

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Position

Assistant professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Maternal Fetal Medicine Research Center

Full name of responsible person

Khadije Bazrafshan

Position

Master

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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