

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Pentoxifylline administration on placenta circulation and pregnancy outcome in Fetal Growth Restriction

Protocol summary

Study aim

Our purpose is to evaluate the effect of pentoxifylline on placenta perfusion by serial Doppler ultrasound assessment of umbilical and uterine arteries and middle cerebral artery

Design

clinical trial with control group; With Parallel groups; Double blinded; randomized; design of 40 patients

Settings and conduct

Patient with fetal growth restriction and abnormal uterine; umbilical and middle cerebral artery Doppler index who are referred to hospitals affiliated Shiraz University of medical sciences underwent weekly Doppler ultrasound evaluation by one expert perinatologist, who is blinded to the study design. Each Doppler is recorded and will compare in 2 groups. Also, the Apgar score, fetal birth weight, and umbilical cord blood gas analysis will compare in both groups at the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with age under 45 Y/o, Gestational age between 26-34 weeks Women with fetal growth restriction and abnormal Doppler finding in uterine; umbilical and middle cerebral artery. Exclusion criteria: high risk pregnancy (Multi fetal pregnancy; premature rupture of membrane; overt diabetes mellitus; Renal failure); Bleeding disorders

Intervention groups

Intervention group: 20 patients will be treated by Pentoxifylline sustained release tablet 400 mg manufactured by Farabi Pharmaceutical Company twice daily from beginning of study up to delivery time. control group: will be received placebo manufactured by Shiraz pharmacy school with the same method.

Main outcome variables

umbilical artery Doppler; uterine artery Doppler; middle cerebral artery; newborn weight; Apgar score; umbilical cord blood gas

General information

Reason for update

Modified approved sample size

Acronym

IRCT registration information

IRCT registration number: **IRCT20140317017034N9**

Registration date: **2019-11-09, 1398/08/18**

Registration timing: **prospective**

Last update: **2021-05-22, 1400/03/01**

Update count: **2**

Registration date

2019-11-09, 1398/08/18

Registrant information

Name

Homeira Vafaei Cisakht

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 2365

Email address

vafaeih@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Pentoxifylline administration on placenta circulation and pregnancy outcome in Fetal Growth Restriction

Public title

Effect of Pentoxifyllin on Fetal Growth Restriction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with age under 45 Y/o Gestational age between 26-34 weeks Women with fetal growth restriction and abnormal finding in uterine or umbilical artery Doppler with stage 1, 2

Exclusion criteria:

High risk pregnancy (Multi fetal pregnancy; premature rupture of membrane; overt diabetes mellitus; Renal failure; preterm labor pain; rheumatoid disease eg:Lupus)) Bleeding disorders

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: use the block; Randomization unit: Individual; Randomization tool: Minitab Statistical software; How to Build a Sequence: Using randomized blocks, block size: 4; Concealment method: Using similar bottles

Blinding (investigator's opinion)

Double blinded

Blinding description

Pentoxifylline and placebo have been administered in the similar bottles, so patients and researchers were unable to detect which one was Pentoxifylline or placebo. Our nurse colleague in this study in Hafez hospital delivered formulations to the participants of the study according to the randomized block table. She was unaware of the content of the bottles. The researcher had no information about formulation used by each patient while visiting them. At the end of the study, the formulations were decoded and the patients assigned to each group were identified.

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

Headquarters Of Shiraz University of Medical Sciences
- Zand St - Shiraz

City

Shiraz

Province

Fars

Postal code

34786-71946

Approval date

2019-06-23, 1398/04/02

Ethics committee reference number

IR.SUMS.REC.1398.559

Health conditions studied**1****Description of health condition studied**

Fetal Growth Restriction

ICD-10 code

P05

ICD-10 code description

Disorders of newborn related to slow fetal growth and fetal malnutrition

Primary outcomes**1****Description**

Umbilical artery Doppler

Timepoint

Doppler ultrasound examination at the beginning of the study and then weekly until the end of the delivery.

Method of measurement

Ultrasound

2**Description**

Birth weight

Timepoint

After birth

Method of measurement

scale

3

Description

Appgar score

Timepoint

After birth

Method of measurement

Metric system

4

Description

Mean PH (Acid or Alkaline) of umbilical cord

Timepoint

After birth

Method of measurement

Blood-gaz-analyzer

5

Description

Uterine artery Doppler

Timepoint

Doppler ultrasound examination at the beginning of the study and then weekly until the end of the delivery.

Method of measurement

Ultrasound

6

Description

Middle cerebral artery Doppler

Timepoint

Doppler ultrasound examination at the beginning of the study and then weekly until the end of the delivery.

Method of measurement

Ultrasound

7

Description

Mean Carbon dioxide pressure of umbilical cord

Timepoint

After birth

Method of measurement

Blood-gaz-analyzer

8

Description

Mean Oxygen pressure of umbilical cord

Timepoint

After birth

Method of measurement

Blood-gaz-analyzer

9

Description

Mean Carbonic Acid of umbilical cord

Timepoint

After birth

Method of measurement

Blood-gaz-analyzer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pentoxifylline sustained release tablet 400 mg manufactured by Farabi Pharmaceutical Company twice daily until delivery

Category

Treatment - Drugs

2

Description

Control group: Placebo twice a day until delivery made by the Faculty of Pharmacy of Shiraz university of medical sciences.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Hafez Clinic of Shiraz University of Medical Sciences

Full name of responsible person

Shoreh Roozme

Street address

Hafez Clinic; Shahid Chamran blvd

City

Shiraz

Province

Fars

Postal code

34786-71946

Phone

+98 71 3612 8257

Email

dr.roozmeh1995@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Yoones Ghasemi

Street address

Building of Shiraz University of Medical Sciences, Zand Ave

City

Shiraz

Province

Fars

Postal code
34786-71946

Phone
+98 71 3235 7282

Email
ghasemiy@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz University of Medical Sciences

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Shohreh Roozme

Position
Fellow ship

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Maternal- Fetal Medicine (Perinatology)research center; Hafez Hospital; Chamran Ave.,Shiraz

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3612 8258

Email
dr.roozmeh1995@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Homeria Vafaei

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Maternal- Fetal Medicine (Perinatology) research center; Hafez Hospital; Chamran Ave., Shiraz

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3612 8258

Email
Vafaeih@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Shohre Roozme

Position
Fellow ship

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Maternal- Fetal Medicine (Perinatology) research center; Hafez Hospital; Chamran Ave., Shiraz

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3612 8258

Email
dr.roozmeh1995@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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

Participant data file: Information and research data Ethic form: Complete the Ethic form by the patient

When the data will become available and for how long

Participant data file: 2019 Ethic form: 2019

To whom data/document is available

Participant data file: Researcher & Patient Ethic form: Patient

Under which criteria data/document could be used

Participant data file: participant's or legal guardian's are

permitted for awareness of the results. Ethic form: participant's or legal guardian's are permitted for awareness of the results.

From where data/document is obtainable

Participant data file: Obstetrics and gynecology ward Shiraz university of medical sciences Ethic form: Obstetrics and gynecology ward Shiraz university of medical sciences

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

Participant data file: Refer to Maternal Fetal medicine Research Center, request for result information. Ethic form: Refer to Maternal Fetal medicine Research Center, request for result information.

Comments