Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Pentoxifiylline administration on placenta circulation and pregnancy out come 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 perinatalogist, 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 Pentoxifiylline administration on placenta circulation and pregnancy out come in Fetal Growth Restriction

Public title
Effect of Pentoxifiyllin 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
Pentoxifiylline and placebo have been administered in the similar bottles, so patients and researchers were unable to detect which one was Pentoxifiylline 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