Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of pomegranate juice with sildenafil on Doppler ultrasound findings in growth restricted fetus

Protocol summary

Study aim
Comparison of the effect of pomegranate juice with sildenafil on Doppler ultrasound findings in fetuses with growth retardation 26 to 32 weeks

Design
This randomized clinical trial with phase 3 parallel groups will be performed on 54 patients with 26 to 32 weeks fetal growth retardation.

Settings and conduct
In this randomized clinical trial study, 54 pregnant women with 26 to 32 weeks gestation with growth retarded fetuses referred to gynecology clinics in the third trimester of pregnancy will be selected by availability. The effect of sildenafil and pomegranate juice on the disorder Intrauterine growth will be monitored.

Participants/Inclusion and exclusion criteria
Inclusion criteria include no underlying diseases, gestational age 26 to 32 weeks and fetuses with growth retardation, singleton cases and willingness to participate in the study. Exclusion criteria also include fetal anomalies and fetal heart problems and the use of antioxidants and special diets .

Intervention groups
One group is given 230 ml of pomegranate juice (equivalent to 8 ounces) daily (20) for up to 6 weeks, in addition to taking the necessary steps mentioned in the obstetrics and gynecology texts (such as taking aspirin). The second group will receive 25 mg of sildenafil 3 tablets daily for 6 weeks and will receive the same care as the first group and aspirin.

Main outcome variables
Doppler ultrasound findings in fetuses with growth retardation;PI umbilical arteryPI; uterine artery;Birth weight of the baby;Apgar score of the baby

General information

Reason for update
Adding FEW as a primary outcome and announcing the completion of the clinical trial

Acronym

IRCT registration information
IRCT registration number: **IRCT20210730052014N1**
Registration date: **2021-10-22, 1400/07/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-03, 1402/04/12**
Update count: **1**

Registration date
2021-10-22, 1400/07/30

Registrant information

Name
Fatemeh Qaedi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3417 3520

Email address
qaediftm@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-21, 1400/06/30

Expected recruitment end date
2022-01-20, 1400/10/30

Actual recruitment start date
2021-09-21, 1400/06/30

Actual recruitment end date
2021-12-22, 1400/10/01

Trial completion date
2022-05-20, 1401/02/30

Scientific title
Comparison of the effect of pomegranate juice with

sildenafil on Doppler ultrasound findings in growth restricted fetus

Public title
Comparison of the effect of pomegranate juice with sildenafil in the treatment of intrauterine growth restriction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No underlying diseases gestational age 26 to 32 weeks fetal developmental delay singleton cases willingness to participate in the study
Exclusion criteria:
fetal anomalies and fetal heart problems consumption of antioxidants and special diets
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **54**
Actual sample size reached: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be allocated into two groups using a permuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/). Concealment is also guaranteed due to the use of permuted balanced block randomization method.
Blinding (investigator's opinion)
Single blinded
Blinding description
The person in charge of statistical analysis will be unaware of the type of intervention performed in the groups and will analyze the data without knowing the type of group allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Deputy of research and technology.,Payambar Azam University Complex.,Arak University of Medical Sciences
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2021-05-09, 1400/02/19
Ethics committee reference number
IR.ARAKMU.REC.1400.023

Health conditions studied

1

Description of health condition studied
Fetal growth restriction
ICD-10 code
O36.5
ICD-10 code description
Maternal care for known or suspected poor fetal growth

Primary outcomes

1

Description
Fetal growth restriction
Timepoint
At the beginning of the study and then monthly
Method of measurement
Changes in umbilical artery PI, uterine artery PI, and estimated fetal weight (FEW) in both groups are monitored and compared monthly by a female resident alongside a perinatologist and radiologist with a Medison device.

Secondary outcomes

1

Description
Birth weight of the baby
Timepoint
At birth
Method of measurement
Using digital scales

2

Description
Apgar score
Timepoint
At birth
Method of measurement

cheaklist

Intervention groups

1

Description
One group, in addition to performing the necessary measures given in the obstetrics and gynecology texts (such as advising to rest, ensuring a proper diet, and receiving aspirin), is given 230 ml of pomegranate juice (equivalent to 8 ounces) daily for up to 6 weeks. It will be provided to patients weekly in calibrated containers for 7 days.
Category
Treatment - Drugs

2

Description
Intervention group: The second group will receive 25 mg of sildenafil 3 tablets daily for 6 weeks and will receive the same care as the first group and aspirin.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital and medical centers affiliated to Arak University of Medical Sciences
Full name of responsible person
Fatemeh Qaedi
Street address
- Taleghani Educational Medical Center.,West side of Imam Khomeini Street next to the gas company
City
Arak
Province
Markazi
Postal code
3816149369
Phone
+98 86 3277 4001
Email
It-taleghani@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
علیرضا کمالی
Street address
Finance Management, Third Floor, Arak University of Medical Sciences, Alma Al-Huda St., Shahid Shiroodi St.
City
Arak
Province
Markazi
Postal code
۳۸۱۹۶۹۳۳۴۵
Phone
+98 86 3312 4955
Fax
Email
dopdarman@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
fatemeh qaedi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Taleghani Educational Medical Center.,West side of Imam Khomeini Street next to the gas company
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Email
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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
En All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Students and researchers can use the data of this study.
From where data/document is obtainable
Researchers can contact the study author via email at qaediftm@gmail.com to receive data and information.
What processes are involved for a request to access data/document
Request information and data to the author via email qaediftm@gmail.com.
Comments