

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

lt-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

۳۸۱۹۶۹۳۳۴۰

##### 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

##### City

Arak

##### Province

Markazi

##### Postal code

3816149369

##### Phone

+98 86 3277 4001

##### Email

qaediftm@gmail.com

## Person responsible for scientific 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

**City**

Arak

**Province**

Markazi

**Postal code**

3816149369

**Phone**

+98 86 3277 4001

**Email**

qaedifm@gmail.com

**Person responsible for updating data****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

**City**

Arak

**Province**

Markazi

**Postal code**

3816149369

**Phone**

+98 86 3277 4001

**Email**

qaedifm@gmail.com

**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 qaedifm@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 qaedifm@gmail.com.

**Comments**