Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of Sildenafil Citrate with melatonin on intrauterine growth restriction

Protocol summary

Study aim
The evaluation of effect the melatonin with Sildenafil on intrauterine fetal growth restriction

Design
clinical trial with control group; With Parallel groups; Double blinded; randomized; design of 88 patients

Settings and conduct
Eligible patients with intrauterine growth restriction and uterine vascular Doppler disorder; umbilical artery midbrain, referring to a gynecology clinic of Yasuj University of Medical Science, divided into four groups of 22 individuals and pregnancy outcomes will be measured.

Participants/Inclusion and exclusion criteria
Single-pregnancy pregnancy with IUGR Pregnancy's age between 26 and 32 weeks Mother's age between 18 to 45 years No using alcohol and cigarettes Normal anomaly scan The absence of fetal with known or suspected anomalies No gestational or chronic diagnosed diabetes Not using other vasodilator drugs such as nitric oxide and calcium channel blockers

Intervention groups
Group A (sildenafil): In this group, sildenafil citrate tablets (Vizarcin), 25 mg orally every eight hours for four weeks. Group B (Melatonin): In this group, melatonin tablets (Razak Pharmaceutical Company, Iran) are prescribed three mg three times a day (morning, lunch, before bed) for four weeks. Group C (sildenafil with melatonin): In this group, the drug dose will be the same as the drug group A and B. Group D: Plasbo drug containing starch is prescribed in the same way as the above intervention groups.

Main outcome variables
Weight percentile Abdominal circumference growth Fetal amniotic fluid index Pregnancy duration Neonate anthropometric measurements (height and weight) Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160524028038N6**
Registration date: **2020-06-30, 1399/04/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-30, 1399/04/10**
Update count: **0**

Registration date
2020-06-30, 1399/04/10

Registrant information

Name
Fatemeh Bazarganipour

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-20, 1398/07/28

Expected recruitment end date
2020-12-20, 1399/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of Sildenafil Citrate with melatonin on intrauterine growth restriction

Public title
Sildenafil Citrate with melatonin and intrauterine growth restriction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Single-pregnancy pregnancy with IUGR Pregnancy's age between 26 and 32 weeks Mother's age between 18 to 45 years No using alcohol and cigarettes Normal anomaly scan The absence of fetal with known or suspected anomalies No gestational or chronic diagnosed diabetes Not using other vasodilator drugs such as nitric oxide and calcium channel blockers
Exclusion criteria:
Lack of follow-up Unwillingness to participate in the study Complications such as premature rupture of membrane, vaginal bleeding, and intrauterine infection Sildenafil sensitivity and tolerance to side effects (flushing, visual disturbances, severe drop in blood pressure and hearing impairment)
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software; Sequence Building: Using randomized 4 in 4 blocks; Hiding method: Use envelopes in the package
Blinding (investigator's opinion)
Double blinded
Blinding description
The blinding method is patients and physicians will not be aware of their allocation to study groups and all medications will be placed into same capsules of size, shape and color by the pharmacist.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town, kohgiluyeh and boyer-ahmad
City
یاسوج
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7916839319
Approval date
2019-10-20, 1398/07/28
Ethics committee reference number
IR.YUMS.REC.1398.129

Health conditions studied

1

Description of health condition studied
Intrauterine 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
Weight percentile
Timepoint
At each visit pregnancy
Method of measurement
Ultrasound

2

Description
Abdominal circumference growth
Timepoint
At each visit pregnancy
Method of measurement
Ultrasound

3

Description
Fetal amniotic fluid index
Timepoint
At each visit pregnancy
Method of measurement
Ultrasound

4

Description
Pregnancy duration
Timepoint
End of pregnancy
Method of measurement
Questionnaire

5

Description
Neonate anthropometric measurements (height and weight)
Timepoint
Delivery time
Method of measurement
Scales and meters

6

Description
Quality of life
Timepoint
End of intervention
Method of measurement
Questionnaire

7

Description
Sleep quality
Timepoint
End of intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Group A (sildenafil): In this group, sildenafil citrate tablets (Vizarcin), 25 mg orally every eight hours for four weeks.
Category
Treatment - Drugs

2

Description
Group B (Melatonin): In this group, melatonin tablets (Razak Pharmaceutical Company, Iran) are prescribed three mg three times a day (morning, lunch, before bed) for four weeks.
Category
Treatment - Drugs

3

Description
Group C (sildenafil with melatonin): In this group, the drug dose will be the same as the drug group A and B.
Category
Treatment - Drugs

4

Description
Group D: Plasbo drug containing starch is prescribed in the same way as the above intervention groups.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Yasuj University of Medical Sciences
Full name of responsible person
Shakiba Amirjani
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Hossein Mari-Oriad
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Grant name

Grant code / Reference number

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

Title of funding source
Yasouj 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
Yasouj University of Medical Sciences

Full name of responsible person
Shakiba Amirjani

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

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Position
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Medical doctor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available