

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

Phone

+98 76 3366 6367

Email address

bazarganipour@hums.ac.ir

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 ياسوج Province Kohgilouyeh-va-Boyerahmad 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

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7916839319

Phone

+98 74 3333 7251

Email

Shakiba.amirjani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Mari-Oriad

Street address

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

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7916839319

Phone

+98 74 3333 7251

Email

Shakiba.amirjani@gmail.com

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

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

City
Yasuj

Province
Kohgiluyeh-va-Boyerahmad

Postal code
7916839319

Phone
+98 74 3333 7251

Email
Shakiba.amirjani@gmail.com

Person responsible for scientific 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

Street address

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

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7916839319

Phone

+98 74 3333 7251

Email

Shakiba.amirjani@gmail.com

Person responsible for updating data

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

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

City

ياسوج

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7916839319

Phone

+98 74 3333 7251

Email

Shakiba.amirjani@gmail.com

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