

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Efficacy of Melatonin in Intrauterine Growth Restriction, A Double blind Randomized Clinical Trial

Protocol summary

Study aim

The Efficacy of Melatonin in Intrauterine Growth Restriction

Design

Double-blind, parallel-group, randomized placebo-controlled trial. Sample size: 66 (33 per group). Block randomization (block size 6), concealed allocation, participants and outcome assessors blinded.

Settings and conduct

Namazi and Hafez Hospitals, Shiraz, Iran. Pregnant women with severe FGR enrolled and followed weekly until delivery. Identical packaging of melatonin and placebo ensures blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: singleton pregnancy; gestational age ≥ 28 weeks; severe FGR (AC < 3 rd centile or < 10 th centile with abnormal Doppler); maternal age ≥ 18 years; written informed consent. Exclusion criteria: current melatonin use; need for immediate delivery; systemic diseases; smoking; melatonin contraindications; maternal/fetal infection; fetal chromosomal/structural anomalies; non-placental FGR

Intervention groups

Prior to the initiation of the study intervention, both the experimental and control groups will be homogenized for key baseline characteristics, including age, BMI, Health-Related Quality of Life (SF-36). The sleep disorder (PSQI) and 36-item quality of life (SF-36) questionnaires will be completed before the start of the intervention and then at monthly intervals until delivery. Intervention: will receive oral tablet melatonin prolonged release 10 mg, three times daily, until delivery Control: will receive placebo (placebo tablet will be manufactured by the faculty of pharmacy, shiraz university of medical sciences), three times daily, until delivery

Main outcome variables

Quality of sleep questionnaire, Estimated fetal weight; Doppler indices (uterine, umbilical, MCA, ductus venosus); birth weight; Apgar scores at 1 and 5 min;

NICU admission; umbilical cord blood gases

General information

Reason for update

With greetings, Change the start date of the patient's from 04/04/2026

Acronym

IRCT registration information

IRCT registration number: **IRCT20170515033976N3**

Registration date: **2026-03-14, 1404/12/23**

Registration timing: **prospective**

Last update: **2026-03-30, 1405/01/10**

Update count: **1**

Registration date

2026-03-14, 1404/12/23

Registrant information

Name

Azam Faraji

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 2365

Email address

farajiaz@sums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-04-04, 1405/01/15

Expected recruitment end date

2026-09-06, 1405/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Melatonin in Intrauterine Growth Restriction, A Double blind Randomized Clinical Trial

Public title

The Efficacy of Melatonin in Intrauterine Growth Restriction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Singleton pregnancy 28 weeks and over of gestation
Intrauterine Growth Restriction

Exclusion criteria:

Current use of melatonin Pregnancies requiring immediate delivery A history of systemic diseases A history of smoking Contraindications to melatonin use

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software Minitab; Sequence Building: Using randomized 46 blocks; Hiding method: Use similar bottles

Blinding (investigator's opinion)

Double blinded

Blinding description

The tablets of both groups are in packets with the same shape, color, size, and other characteristics, and the patients are randomly assigned to one of the placebo or Melatonin groups, and intake continues at the same dose until the end of pregnancy. In group A, patients are prescribed Melatonin tablets manufactured by Abidi Pharmaceutical Company and for group B three placebo tablets (placebo tablets will be manufactured by the Faculty of Pharmacy, Shiraz University of Medical Sciences).

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

7194634786

Approval date

2026-02-02, 1404/11/13

Ethics committee reference number

IR.SUMS.MED.REC.1404.596

Health conditions studied**1****Description of health condition studied**

Intrauterine Growth Restriction (IUGR) / Fetal Growth Restriction (FGR)

ICD-10 code

P05

ICD-10 code description

Disorders of newborn related to slow fetal growth and fetal malnutrition

Primary outcomes**1****Description**

Estimated fetal weight

Timepoint

weekly

Method of measurement

Sonography

2**Description**

Fetal Doppler

Timepoint

weekly

Method of measurement

Sonography

3**Description**

Birth weight
Timepoint
After birth
Method of measurement
Scale

Secondary outcomes

1
Description
Umbilical cord blood gases
Timepoint
After birth
Method of measurement
Analyzer

Intervention groups

1
Description
Intervention group: Oral prolonged-release melatonin tablets, 10 mg, three times daily, from enrolment until delivery. Manufacturer: Abidi Pharmaceutical Company, Iran.
Category
Treatment - Drugs

2
Description
Control group: Oral placebo tablets identical in appearance (shape, color, size), three times daily, from enrolment until delivery. Manufacturer: Faculty of Pharmacy, Shiraz University of Medical Sciences, Iran.
Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Haspial affiliated to Shiraz university of medical sciences
Full name of responsible person
Azam Faraji
Street address
Maternal- Fetal Medicine (Perinatology), Hafez Hospital, Chamran Ave., Shiraz, Iran
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farajiaz@sums.ac.ir

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
Building of Shiraz University of Medical Sciences, Zand Ave
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7194634786
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Email
mohammadi@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
Elham Gorjipour
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Azam Faraji

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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34786-71946

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Email

farajiaz@sums.ac.ir

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Information and research data Ethic form: Complete the Ethic form by the patient

When the data will become available and for how long

IPD: 2025, Ethic form: 2026

To whom data/document is available

IPD: Researcher & Patient Ethic form: Patient

Under which criteria data/document could be used

IPD: Ethic form: Awareness of test results

From where data/document is obtainable

IPD: OB & Gyn ward Shiraz university of medical sciences
Ethic form: OB & Gyn ward Shiraz university of medical sciences

What processes are involved for a request to access data/document

IPD: Vice chancellery Ethic form: Vice chancellery

Comments