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 <3rd centile or <10th 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-۳۶). The sleep disorder (PSQI) and ۳۶-item quality of life (SF-۳۶) 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 ۱۰ 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 birh

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

City

Shiraz

Province

Fars

Postal code

7184837786

Phone

+98 71 3647 9830

Email

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

City

Shiraz

Province

Fars

Postal code

7194634786

Phone

+98 71 3235 7282

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

Street address

Maternal- Fetal Medicine (Perinatology)research center; Hafez Hospital; Chamran Ave.,Shiraz

City

Shiraz

Province

Fars

Postal code

7194634786

Phone
+98 71 3647 9830

Email
e.gorjipour۲···@gmail.com

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
Gynecology and Obstetrics

Street address
Maternal- Fetal Medicine (Perinatology) research center; Hafez Hospital; Chamran Ave., Shiraz

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3647 9830

Email
farajiaz@sums.ac.ir

Person responsible for updating data

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
Gynecology and Obstetrics

Street address
Maternal- Fetal Medicine (Perinatology) research center; Hafez Hospital; Chamran Ave., Shiraz

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3647 9830

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