Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of melatonin in fetal pulmonary artery doppler index and a role of this parameters in prevention of neonatal respiratory distress syndrome in preterm neonates with maternal abnormal implantation placenta

Protocol summary

Study aim

Investigating the effect of melatonin on fetal pulmonary artery doppler indices and prevention of fetal distress syndrome in pregnancy with placental implantation disorders

Design

64 of these people are randomly divided into two groups treated with melatonin for two weeks with a daily dose of 10 mg and the group without treatment (control) melatonin. Study phase 2-3; The basis of the formula for determining the sample size based on multiple regression was equal to 29 in each group to compensate for missing items. 3 people were added in each group and a total of 32 people were selected in each group. Blocked randomization method will be used for the random allocation of intervention and control groups. The number of blocks will be four and will be named as codes a and b. How to select eligible women will be available in the method.

Settings and conduct

All pregnant women aged 19 to 45 with singletons referred to Imam Khomeini Hospital in Tehran in 2023 without fetal anomalies with a gestational age of 32-34 weeks with placental disorders without any other underlying disease are included in the study. These people are randomly divided into two groups treated with melatonin and the group without melatonin treatment. Melatonin tablets 10 mg daily before going to bed for a period of 2 weeks for each patient who is in the melatonin group. The sample is 64 people, 32 people are in the group with melatonin and 32 people are in the group without melatonin.

Participants/Inclusion and exclusion criteria

All pregnant women aged 19 to 45 with singletons without fetal anomalies with a gestational age of 32-34 weeks with placental disorders without any other underlying disease.

Intervention groups

Groups treated with melatonin for two weeks at a dose of 10 mg daily and the group without melatonin treatment.

Main outcome variables

Fetal Pulmonary Artery Doppler; Respiratory Distress Rate; Neonate Apgar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230801059003N1**
Registration date: **2023-08-16, 1402/05/25**
Registration timing: **prospective**

Last update: **2023-08-16, 1402/05/25**
Update count: **0**

Registration date

2023-08-16, 1402/05/25

Registrant information

Name

Bahar Farshidfar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-21, 1402/06/30

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of melatonin in fetal pulmonary artery doppler index and a role of this parameters in prevention of neonatal respiratory distress syndrome in preterm neonates with maternal abnormal implantation placenta

Public title

Efficacy of melatonin in fetal pulmonary artery doppler index and a role of this parameters in prevention of neonatal respiratory distress syndrome in preterm neonates with maternal abnormal implantation placenta

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Singleton pregnant women with gestational age of 32-34 weeks with placental disorders (acreta, increta, percreta, previa)

Exclusion criteria:

Fetal anomaly Mother's underlying disease

Age

From **19 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization method will be used for randomly assigning the intervention and control groups. The number of blocks will be four and will be in the form of code a and b.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences Headquarters, Qods Corner, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2023-07-19, 1402/04/28

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.164

Health conditions studied

1

Description of health condition studied

Preterm neonates

ICD-10 code

O60.3

ICD-10 code description

Preterm delivery by: caesarean section, without spontaneous labour

2

Description of health condition studied

Infant respiratory distress

ICD-10 code

P22.8

ICD-10 code description

Other respiratory distress of newborn

Primary outcomes

1

Description

Pulmonary artery Doppler of the fetus

Timepoint

2 weeks

Method of measurement

Philips ultrasound

2

Description

Apgar minutes 1 and 5

Timepoint

Day 1, birthday, minutes 1 and 5

Method of measurement

clinical

3

Description
The degree of respiratory distress of the infant
Timepoint
day 1 birthday
Method of measurement
clinical

4

Description
Middle cerebral artery Doppler
Timepoint
2 weeks
Method of measurement
Philips ultrasound

5

Description
Doppler of the umbilical artery
Timepoint
2 weeks
Method of measurement
Philips ultrasound

6

Description
Uterine artery doppler
Timepoint
2 weeks
Method of measurement
Philips ultrasound

7

Description
Neonatal resuscitation
Timepoint
First day after birth
Method of measurement
clinical

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 19 to 45-year-old singleton pregnant women without fetal anomalies with a gestational age of 32-34 weeks with placental disorders (ecreta, increta, percreta, previa) without any other underlying disease will be included in the study. Melatonin tablets of 10 mg (2 tablets of 5 mg) are given daily before going to bed for a period of 2 weeks. The sample number is 64 people, of which 32 people are in this group (melatonin consumption group). Doppler examination of the pulmonary artery by measuring AT/ET in ultrasound is done before the start of melatonin treatment once and again the day before delivery, and the baby is evaluated after birth, and the results of the Doppler indices are compared with the condition of the baby in two groups.
Category
Prevention

2

Description
Control group: Control group: 19-45-year-old singleton pregnant women without fetal anomalies with a gestational age of 32-34 weeks with placental disorders (ecreta, increta, precreta, previa) without any other underlying disease will be included in the study. This group will not be treated with melatonin tablets, and there are 32 people in this group (group without melatonin). Pulmonary artery doppler examination by measuring ET (ejection time) AT (acceleration time) AT/ET is performed in ultrasound once a day before delivery and the baby is evaluated after birth and the results of pulmonary artery doppler indices are compared with the condition of the baby after birth. will be
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex- Tehran University of Medical Sciences
Full name of responsible person
Bahar Farshidfar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
الهه محمدی
Street address

Keshavarz Blvd., Naderi St., Hojat Dost St., No. 57

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hperc@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Bahar Farshidfar

Position
Obstetrics and Gynecology Fellowship

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Position
Obstetrics and Gynecology Fellowship

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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
Intellectual Property/Confidentiality Issues/Ethical Concerns

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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available