Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Investigating of the adjuvant effect of melatonin in the prevention of preeclampsia in moderate and high risk women

Protocol summary

Study aim
Determination of the auxiliary effect of melatonin in the prevention of preeclampsia in women with moderate and high risk

Design
The clinical trial has a control group with a parallel intervention group in a blinded three-way, simple randomized block, phase 2-3 on 120 patients, rand excel function is used for randomization.

Settings and conduct
Shahid Beheshti Hospital, Kashan

Participants/Inclusion and exclusion criteria
Inclusion criteria 16 years and older 12-28 weeks of pregnancy moderate to high risk of preeclampsia based on US Preventive Services Task Force criteria Having informed consent Exclusion criteria Multiple pregnancy Current or previous use of melatonin in the past 6 weeks Allergy to melatonin and aspirin Use of any of the following drugs that can interfere with the metabolism and/or elimination of melatonin: fluvoxamine, 5- or 8-methoxypsoralen, cimetidine, quinolones, and other CYP1A2 inhibitors. Carbamazepine, rifampicin and other CYP1A2 inducers. and zalplon, zolpidem, zopiclone, and other non-benzodiazepine hypnotics. lose to follow-up non cooperate The presence of any disease or condition that is a contraindication for continued pregnancy Fetal anomaly

Intervention groups
Taking aspirin with melatonin

Main outcome variables
Occurrence of preeclampsia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230930059563N1**
Registration date: **2023-12-30, 1402/10/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-30, 1402/10/09**
Update count: **0**

Registration date
2023-12-30, 1402/10/09

Registrant information

Name
Mozhgan Alishahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5500 9999

Email address
alishahimozhgan@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-26, 1402/09/05

Expected recruitment end date
2024-01-25, 1402/11/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating of the adjuvant effect of melatonin in the prevention of preeclampsia in moderate and high risk women

Public title
The effect of melatonin in the prevention of preeclampsia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

16 years and older 12-28 weeks of pregnancy moderate to high risk of preeclampsia based on US Preventive Services Task Force criteria informed consent

Exclusion criteria:

Multiple pregnancy Current or previous use of melatonin in the past 6 weeks Allergy to melatonin and aspirin Use of any of the following drugs that can interfere with the metabolism and/or elimination of melatonin: fluvoxamine, 5- or 8-methoxypsoralen, cimetidine, quinolones, and other CYP1A2 inhibitors. Carbamazepine, rifampicin and other CYP1A2 inducers. and zalplon, zolpidem, zopiclone, and other non-benzodiazepine hypnotics. lose to follow-up non cooperate The presence of any disease or condition that is a contraindication for continued pregnancy Fetal anomaly

Age

From **16 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be using random allocation in blocks of 6. Thus, in each block of 6, 3 patients will be in the intervention group and 3 patients will be in the control group. At the beginning of block selection, patients are selected by simple random method using random numbers until the chance of accepting the patient in the block is 100%, in which case patients are selected in that group to complete the block.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Both groups will receive the drugs in the same packaging, size and box. The codes will remain with one of the colleagues of the research project and will be decoded at the end of the study. None of the presenters and patients know the type of codes of each patient until after the data analysis, thus this study is conducted in a triple blind manner.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Hekmat 55 Street, Qutb Rawandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8715973474

Approval date

2023-09-10, 1402/06/19

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.138

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

O14.9

ICD-10 code description

Unspecified pre-eclampsia

Primary outcomes

1

Description

Occurrence of preeclampsia

Timepoint

The time interval until the occurrence of pre-eclampsia or termination of pregnancy, whichever is earlier.

Method of measurement

Based on clinical examination

Secondary outcomes

1

Description

Type of delivery

Timepoint

Once upon a time

Method of measurement

clinical basis

2

Description

neonate Apgar

Timepoint

Once at the moment of the birth

Method of measurement

Based on the Apgar scoring system

3

Description

Newborn characteristics (height-weight)

Timepoint

Once at the moment of the birth

Method of measurement

Based on the standard method of measuring the height and weight of the baby

Intervention groups

1

Description

Intervention group: Aspirin + melatonin

Category

Prevention

2

Description

Control group: Aspirin

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان شهید بهشتی کاشان

Full name of responsible person

مژگان علیشاهی

Street address

Hekmat 55 Alley, Qutb Rawandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8715973474

Phone

+98 31 5558 9444

Email

info@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Hamidi

Street address

کاشان، بلوار قطب راوندی، کوچه حکمت ۵۵

City

Kashan

Province

Isfehan

Postal code

8715988141

Phone

+98 31 5558 9399

Email

hamidi_gh@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mozhgan Alishahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Hekmat 55 Alley, Qutb Rawandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8715988141

Phone

+98 31 5558 9338

Email

alishahimozhgan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
مرضیه طالبیان
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Hekmat 55 Alley, Qutb Rawandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5558 9444
Email
talebianm861@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Mozhgan Alishahi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Hekmat 55 Alley, Qutb Rawandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 935 550 2153
Email
alishahimozhgan@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Title and more details about the data/document
Age, body mass index, blood pressure, baby weight, number of pregnancies, nationality, education, gestational age at arrival, gestational age at delivery, treatment group, type of delivery, occurrence of pre-eclampsia, baby Apgar, baby height, baby head circumference
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Use for the purpose of meta-analyses is allowed. In other matters, it is necessary to obtain permission from the owner of the license.
From where data/document is obtainable
Hekmat 55 Alley, Qutb Rawandi Boulevard, Kashan Obstetrics and Gynecology Group 00983155589444
What processes are involved for a request to access data/document
Call or send a request to the Obstetrics and Gynecology Department of Kashan University of Medical Sciences
Comments