Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effects of melatonine on the levels of oxidative stress and inflammatory markers in high risk pregnant women receiving enoxaparin and aspirin

Protocol summary

Study aim

The effects of melatonin in high risk pregnant women receiving enoxaparin and aspirin

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 50 people. For randomization, block design is used.

Settings and conduct

Referred to the Imam Sajad hospital of Yasouj city in 2021, selection of 50 individuals based on inclusion and exclusion criteria, randomization into intervention and control groups, perform the intervention for 20 weeks, taking 5 cc of blood before the intervention and after the intervention. For blinding and unawareness of doctor, researcher, and individuals, unique codes will be used on the drug boxes. Melatonin and placebo tablets will be placed into identical containers by an independent third party. Participants will be entered into study based on the produced sequence. The drug packets will be allocated to the individual with code on them. Therefore, participants will be unaware of the type of intervention that will receive, as well as the random sequence which will be hidden and unpredictable.

Participants/Inclusion and exclusion criteria

Inclusion: Pregnant women 15 to 45 years old؛ Gestational age between 6 to16 weeks؛ BMI more than 25 kg/m2 Exclusion: Chronic metabolic diseases؛ Smokers and alcoholics؛ Use of other dietary supplements and anti-inflammatory drugs؛ History of taking OCP pills؛ Twin pregnancies or more

Intervention groups

Intervention group: Two 3-mg melatonin tablets per day, 1h before bedtime for 20 weeks with 40 mg daily enoxaparin and 80 mg daily aspirin. Control group: Two tablets of 3-mg placebo/day (containing starch), 1 h before bedtime for 20 weeks with 40 mg daily enoxaparin and 80 mg daily aspirin.

Main outcome variables

Serum levels of total antioxidant capacity؛ malondialdehyde؛ nitric oxide metabolites؛ sulfhydryl protein؛ C-reactive protein؛ baby weight؛ baby head circumference and baby height

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210608051518N1**
Registration date: **2021-12-22, 1400/10/01**
Registration timing: **prospective**

Last update: **2021-12-22, 1400/10/01**
Update count: **0**

Registration date

2021-12-22, 1400/10/01

Registrant information

Name
Parvinsadat Eslamnik
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 4643 2157
Email address
p.eslamnik284@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of melatonine on the levels of oxidative stress and inflammatory markers in high risk pregnant women receiving enoxaparin and aspirin

Public title
The effects of melatonine in high risk pregnant women receiving enoxaparin and aspirin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women 15 to 45 years old Gestational age between 6 to16 weeks BMI more than 25 kg/m2 Start of taking anticoagulants and aspirin from the first half of pregnancy
Exclusion criteria:
Patients with diabetes mellitus receiving insulin or oral tablets Chronic metabolic diseases Anemia Smokers and alcoholics Use of other dietary supplements, probiotics and anti-inflammatory drugs Use of any antioxidant supplements in the last 3 months Use of immunosuppressive drugs Following of special diets History of taking OCP pills Twin pregnancies or more Gestational hypertension and diabetes
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomized allocation performing, permuted block randomization will be used by quadrilateral blocks. According to the sample size, blocks will be generated using the online site (www.sealedenvelope.com). Participants will be entered into study based on the produced sequence. The drug packets will be allocated to the individual with code on them. Therefore, participants will be unaware of the type of intervention that will receive, as well as the random sequence which will be hidden and unpredictable.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding and unawareness of doctor, researcher, and individuals, unique codes will be used on the drug boxes. Melatonin and placebo tablets will be placed into identical containers by an independent third party. Participants will be entered into study based on the produced sequence. The drug packets will be allocated to the individual with code on them. Therefore, participants will be unaware of the type of intervention that will receive, as well as the random sequence which will be hidden and unpredictable.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Yasuj University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Yasuj University of Medical Sciences, Motahhari Blvd., Kohgiluyeh and Boyerahmad, Yasuj, Iran
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
٤٢٥٠٩٣١٦٠٩
Approval date
2021-06-02, 1400/03/12
Ethics committee reference number
IR.YUMS.REC.1400.053

Health conditions studied

1

Description of health condition studied
High risk pregnant women receiving prophylaxis enoxaparin and aspirin
ICD-10 code
Z34.8
ICD-10 code description
Encounter for supervision of other normal pregnancy

Primary outcomes

1

Description
C-reactive protein
Timepoint

Before and after the intervention
Method of measurement
ELISA

Secondary outcomes

1

Description
Total antioxidant capacity
Timepoint
Before and after the intervention
Method of measurement
ELISA

2

Description
Malondialdehyde (MDA)
Timepoint
Before and after the intervention
Method of measurement
ELISA

3

Description
Nitric oxide metabolites
Timepoint
Before and after the intervention
Method of measurement
ELISA

4

Description
Sulfhydryl protein
Timepoint
Before and after the intervention
Method of measurement
ELISA

5

Description
Baby head circumference
Timepoint
After the delivery
Method of measurement
Tape meter

6

Description
Baby height
Timepoint
After the delivery
Method of measurement
Digital scales

7

Description
Baby weight
Timepoint
After the delivery
Method of measurement
Digital scales

Intervention groups

1

Description
Intervention group: Two 3-mg melatonin tablets per day, 1 h before bedtime for 20 weeks, made by Nature Made, USA with 40 mg daily enoxaparin and 80 mg daily aspirin.
Category
Treatment - Drugs

2

Description
Control group: Two tablets of 3-mg placebo/day (containing starch), 1 h before bedtime for 20 weeks, provided by the school of Pharmacy at Yasuj University of Medical Sciences with 40 mg daily enoxaparin and 80 mg daily aspirin.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sajad hospital, Yasuj
Full name of responsible person
Dr.Roghaye Porhemmat
Street address
Yasuj University of Medical Sciences, Motahhari Blvd., Kohgiluyeh and Boyerahmad, Yasuj, Iran
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
2380083861
Phone
+98 74 3323 0290
Email
roghiporhemmat@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr. Hossein Marioryad
Street address

Vice Chancellor for Research and Technology, Yasuj University of Medical Sciences, Motahhari Blvd., Kohgiluyeh and Boyerahmad, Yasuj, Iran

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
6079-3334-074

Phone
+98 74 3343 6078

Email
roghiporhemmat@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice Chancellor for Research and Technology of Yasuj 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
Dr. Roghaye Porhemmat

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Yasuj University of Medical Sciences, Motahhari Blvd., Kohgiluyeh and Boyerahmad, Yasuj, Iran

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
07433346079

Phone
+98 74 3334 6078

Email
roghiporhemmat@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Dr. Parvin sadat Eslamnik

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Yasuj University of Medical Sciences, Motahhari Blvd., Kohgiluyeh and Boyerahmad, Yasuj, Iran

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
07433346079

Phone
+98 74 3334 6078

Email
p.eslamnik284@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Dr.Roghaye Porhemmat

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Yasuj University of Medical Sciences, Motahhari Blvd., Kohgiluyeh and Boyerahmad, Yasuj, Iran

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Phone
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Email
roghiporhemmat@yahoo.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
The person's information will be confidential and the results will be as collective statistics

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

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Not applicable

Data Dictionary
Not applicable