

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of melatonin 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 to 16 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 melatonin on the levels of oxidative stress and inflammatory markers in high risk pregnant women receiving enoxaparin and aspirin

Public title

The effects of melatonin 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 to 16 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-Boyerahmad

Postal code

۷۲۵۰۹۳۱۶۰۹

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

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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.,
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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**

Yasuj 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.,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yasuj University of Medical Sciences

Full name of responsible person

Dr. Parvin sadat Eslamnik

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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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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