Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effect of using and not using of melatonin on prevention of patients' postpartum uterus bleeding after normal vaginal delivery

Protocol summary

Summary

Objectives: The results of investigators’ findings show that Melatonin hormone has a synergic effect with Oxytocin hormone in increasing uterus contractions during delivery and prevention of postpartum atony. The aim of the present study is to assess the effect of Melatonin on prevention of postpartum hemorrhage. Design: 140 term pregnant women will enter the study. After evaluating primary levels of serum hemoglobin and hematocrit, the patients will be randomly divided into two groups (control or intervention). Setting and conduct: The patients in the control group will receive only the standard treatment for uterus bleeding, i.e. Oxytocin intravenous fluid. The patients in the intervention group will receive the same treatment plus 3 doses of Melatonin tablets sublingually. Major Inclusion and Exclusion criteria: Term pregnant women with simultaneous labor pain and hemoglobin level above 10 mg/dl without history of underline disease and need for delivery induction, cesarean section or blood transfusion. Intervention: Receiving or not receiving Melatonin Main outcome measures (variables): Until 24 hours after delivery the patients’ serum hemoglobin and hematocrit levels will be evaluated and compared with the primary levels.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050919037N9**
Registration date: **2015-06-01, 1394/03/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-01, 1394/03/11

Registrant information

Name
Mahdieh Yousef-Zanjani
Name of organization / entity
Qazvin University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-12-01, 1393/09/10

Expected recruitment end date

2015-05-31, 1394/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of using and not using of melatonin on prevention of patients' postpartum uterus bleeding after normal vaginal delivery

Public title

Evaluation of the effect of Melatonin on prevention of postpartum bleeding

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Term pregnant women with simultaneous labor pain and hemoglobin level above 10 mg/dl. Exclusion criteria: History of underline disease, dystocia, multiparity, chorioamnionitis and need for delivery induction, cesarean section or blood transfusion.
Age
From **18 years** old to **30 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Participants will be divided into two groups (control or intervention) using random number tables.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin university of medical sciences
Street address
Shahid Bahonar Boulevard
City
Qazvin
Postal code
Approval date
2014-06-02, 1393/03/12
Ethics committee reference number
28.20.8835

Health conditions studied

1

Description of health condition studied
Postpartum haemorrhage
ICD-10 code
O72
ICD-10 code description
haemorrhage after delivery of fetus or infant

Primary outcomes

1

Description
Serum hemoglobin level
Timepoint
Until 24 hours after delivery (every 6 hours)
Method of measurement
Blood sampling test

2

Description
Serum hematocrit level
Timepoint
Until 24 hours after delivery (every 6 hours)
Method of measurement
Blood sampling test

Secondary outcomes

1

Description
Blood pressure
Timepoint
Until 6 hours after delivery, every 2 hours
Method of measurement
Monitor device

2

Description
Heart rate
Timepoint
Until 6 hours after delivery, every 2 hours
Method of measurement
Monitor device

Intervention groups

1

Description
Group 1 (control): Only the usage of needed dosage of Oxytocin intravenous fluid (common and standard treatment) for prevention of postpartum hemorrhage
Category
Prevention

2

Description
Group 2 (intervention): Receive 3 doses of Melatonin sublingually: 6 mg at 7 cm dilatation, 3 mg after fetus exit and 3 mg 1 hour after delivery. (Tablet Melatonin 3 mg from NatureMade company, The USA) Plus Usage of needed dosage of Oxytocin intravenous fluid (common and standard treatment) for prevention of postpartum

hemorrhage

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Obstetrics and Gynecology Hospital

Full name of responsible person

Dr. Ezzatossadat Haj Seyyed Javadi

Street address

Kosar Street, Ayatollah Taleghani Boulevard

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Dr. Mahour Kamali

Street address

Kosar Hospital, Kosar Street, Ayatollah Taleghani Boulevard

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kosar Obstetrics and Gynecology Hospital

Full name of responsible person

Dr. Mahour Kamali

Position

Obstetrics and Gynecology resident

Other areas of specialty/work

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dr.kamali82@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin university of medical sciences

Full name of responsible person

Dr. Ezzatossadat Haj Seyyed Javadi

Position

Assistant professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mahdieh Yousef-Zanjani

Position

Other areas of specialty/work

Street address

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty