

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3333 6004

###### Email address

yusefi.mahdieh@yahoo.com

##### 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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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
Assistant professor  
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**Street address**  
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## Person responsible for updating data

### Contact

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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*