

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Study the effect of Melatonin on postoperative pain and blood loss after cesarean section

#### Protocol summary

##### Summary

To assess effect of melatonin on pain and amount of blood loss after cesarean delivery one hundred twenty women with singleton term pregnancy undergoing elective or emergency lower segment cesarean section under spinal anesthesia were included in this study. The patients were randomly allocated to one of three groups of 40 each to receive sublingual 3 mg melatonin or 6 mg melatonin or placebo before spinal of anesthesia . In all patients 20 IU syntocinon which dissolved in 0.5liter of lactated Ringer's solution) at the rate of 500 ml over a 15 minutes period, immediately after delivery of the neonate was infused . Time to first requirement of analgesic supplement, Hemodynamic variables,will be recorded.Patients were instructed preoperatively in the use of the verbal rating scale (VRS) from 0 to 10 (0no pain, 10maximum imaginable pain) for pain assessment. If the VRS exceeded four and the patient requested a supplement analgesic, diclofenac Na supp 100 mg was to be given for post-operative pain relief as needed . For breakthrough pain(VRS >4) if time of administration of diclofenac Na less than 8h,Pethidine 25 mg IV was given. For determination of blood loss ,change in hemoglobin levels, need for additional oxytocics and ,the volume of blood in the suction bottle was measured, blood soaked sponges. Hemoglobin values were determined both before surgery and 12 h following surgery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012120411665N1**  
Registration date: **2013-01-26, 1391/11/07**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-01-26, 1391/11/07

##### Registrant information

###### Name

Morteza Delkhosh Reihany

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Qazvin University of Medical Sciences

##### Expected recruitment start date

2011-12-26, 1390/10/05

##### Expected recruitment end date

2012-12-25, 1391/10/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study the effect of Melatonin on postoperative pain and blood loss after cesarean section

##### Public title

Evaluation of melatonin's effect on pain and blood loss after cesarean section

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: pregnant women at term (37–40 wks);

cesarean section;spinal anesthesia; with out current or previous history of significant disease including heart disease, liver, renal disorders or known coagulopathy. Excluding criteria: Anemia (Hb8 g%); multiple gestation; antepartum hemorrhage; poly-hydramnios; two or more previous cesarean sections; a history of previous rupture uterus.

#### Age

From **18 years** old to **40 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

### 1

#### Registry name

Australian New Zealand Clinical Trials Registry

#### Secondary trial Id

ACTRN12612000117819

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Qazvin University of Medical Sciences

##### Street address

Qazvin University of Medical Sciences, Bahonar ave.

##### City

Qazvin

##### Postal code

3419759811

#### Approval date

2011-12-26, 1390/10/05

#### Ethics committee reference number

d/20/3893

## Health conditions studied

### 1

#### Description of health condition studied

postoperative hemorrhage

#### ICD-10 code

T81.0

#### ICD-10 code description

Haemorrhage and haematoma complicating a procedure, not elsewhere classified

## Primary outcomes

### 1

#### Description

amount of blood loss after cesarean delivery

#### Timepoint

determination of Hemoglobin values both before surgery and 12 h following surgery

#### Method of measurement

determination of Hemoglobin values

### 2

#### Description

Time to first requirement of analgesic supplement

#### Timepoint

Time to first requirement of analgesic supplement from the time of injection intrathecal anesthetic solution

#### Method of measurement

Verbal Pain Scale[ VRS]>4

## Secondary outcomes

### 1

#### Description

hemodynamic variables

#### Timepoint

hemodynamic variables 5min before the intrathecal injection,and at 2, 4, 6, 10, 15,20 ,25,30 min after the injection

#### Method of measurement

measurement by noninvasive automatic blood pressure

### 2

#### Description

severity of anxiety

#### Timepoint

5min before the intrathecal injection,and at 2, 4, 6, 10, 15,20 ,25,30 min after the injection

#### Method of measurement

(VAS)Visual Anxiety Scale

## Intervention groups

### 1

#### Description

Patient received sublingual melatonin 3mg , single dose, 15-20 min before spinal anesthesia .

**Category**

Treatment - Drugs

**2****Description**

Patient received sublingual melatonin 6mg, single dose, 15-20min before spinal anesthesia.

**Category**

Treatment - Drugs

**3****Description**

Patient received sublingual placebo , single dose , 15-20min before spinal anesthesia

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kosar Hospital

**Full name of responsible person**

Morteza Delkhosh Reihany

**Street address**

Talegany ave.

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Shafi Khany

**Street address**

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**City**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Qazvin University of Medical Sciences

**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**

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Professional Assistant

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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*