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 determiniation 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

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Morteza Delkhosh Reihany
Name of organization / entity
Qazvin University of Medical Sciences
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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;spainal 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 nonivasive 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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Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Shafi Khany
Street address
Qazvin University of Medical Sciences
City
Qazvin
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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Person responsible for updating data

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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