Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A double-blind randomized placebo - controlled trial of melatonin as premedication agent in Caesarean section

Protocol summary

Study aim
To investigate the impact of melatonin as a premedication agent in Caesarean section on blood loss and pain level postoperative.

Design
We randomly allocated them every group has 40 patients, melatonin group (M) and placebo group (P). The dose was given to patient at the night and 90 minutes before the operation (10 mg) sublingually per doses

Settings and conduct
A double-blind randomized placebo - controlled trial

Participants/Inclusion and exclusion criteria
: age exceeding 18 years, categorized as ASA I or ASA II (pertaining to the American Society of Anesthesiologists Physical Status Classification System, signifying a patient in good health or with mild systemic illness, respectively), pregnancy at a gestational age surpassing 37 weeks exclusions criteria which indicates severe systemic disease or a constant threat to life, documented drug allergy to melatonin or any other study medications, contraindications for spinal anesthesia such as spinal abnormalities or infections, inability of the patient to respond or demonstrate awareness to the questions rose

Intervention groups
Prior to subarachnoid block administration, all subjects were administered a lactated Ringer's solution intravenous preload , a Quincke needle with a gauge of 25 are used while the patient was in a seated position. oxytocin was administered intravenously Haemoglobin levels were assessed prior to and 12 hours subsequent to the surgical procedure. In addition to the pre- and post-surgery haemoglobin level changes, blood loss was assessed using two methods: a) the weight difference of materials used before and after surgery, and b) the volume of blood collected in the suction bottle following placental delivery, both measured in milliliters (ml).

Main outcome variables
anxiety sedation blood loss postoperative opioid conception postoperative pain intensity

General information

Reason for update

Acronym
EMSC

IRCT registration information
IRCT registration number: **IRCT20230809059105N1**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**
Update count: **0**

Registration date
2023-08-21, 1402/05/30

Registrant information

Name
Hussein Alkhfaji

Name of organization / entity
Alayen university

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Iraq

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-25, 1402/06/03

Expected recruitment end date
2024-05-30, 1403/03/10

Actual recruitment start date
2023-08-25, 1402/06/03

Actual recruitment end date

2024-05-30, 1403/03/10

Trial completion date

2024-10-30, 1403/08/09

Scientific title

A double-blind randomized placebo - controlled trial of melatonin as premedication agent in Caesarean section

Public title

effects of melatonin as premedication agent in caesarean section

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The study's inclusion criteria encompassed individuals who fulfilled the subsequent requirements: age exceeding 18 years, categorized as ASA I or ASA II (pertaining to the American Society of Anesthesiologists Physical Status Classification System, signifying a patient in good health or with mild systemic illness, respectively), pregnancy at a gestational age surpassing 37 weeks, unbroken membranes, scheduled surgical procedures, patient agreement and contentment with study participation, and women with a solitary pregnancy.

Exclusion criteria:

The exclusion criteria for the study encompass several factors, including ASA III or higher, which indicates severe systemic disease or a constant threat to life, documented drug allergy to melatonin or any other study medications, contraindications for spinal anesthesia such as spinal abnormalities or infections, inability of the patient to respond or demonstrate awareness to the questions rose, a history of mental or neurological diseases that could affect the patient's ability to participate or comprehend the study procedures, addiction to substances that could interfere with the study outcomes, disapproval or dissatisfaction expressed by the patient regarding their involvement in the study, presence of congenital malformations in the fetus detected during routine prenatal screening, inability to provide informed consent due to intellectual impairment or other factors, significant heart disease that could pose additional risks during the surgical procedure.

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

An epidemiologist, who was not considered a participant in the clinical trial, will set up a random sequence for the purpose of arranging the administration of the substance used in the study, randomization will occur on a 1:1 ratio of melatonin to placebo, and deliver it to a second person who does not know the exact substance content, as they do not Participating in the clinical study as well, also not recruited by the epidemiologist who prepared the random sequencing. Both melatonin and placebo tablets are indistinguishable and will be contained in bags individually prepared by an epidemiologist. The researcher and all participants will not be able to distinguish the type of drug that was administered to the patient. At the time of assigning study participants, the symbol appearing on the treatment bag that was administered to the patient will be identified on the assessment form. Then, all data and tissue samples collected from the participant will be classified and stored only using this code associated with the randomly distributed treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

An epidemiologist, who was not considered a participant in the clinical trial, will set up a random sequence for the purpose of arranging the administration of the substance used in the study, randomization will occur on a 1:1 ratio of melatonin to placebo, and deliver it to a second person who does not know the exact substance content, as they do not Participating in the clinical study as well, also not recruited by the epidemiologist who prepared the random sequencing. Both melatonin and placebo tablets are indistinguishable and will be contained in bags individually prepared by an epidemiologist. The researcher and all participants will not be able to distinguish the type of drug that was administered to the patient. At the time of assigning study participants, the symbol appearing on the treatment bag that was administered to the patient will be identified on the assessment form. Then, all data and tissue samples collected from the participant will be classified and stored only using this code associated with the randomly distributed treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Impact of melatonin as a premedication agent in Caesarean section on blood loss and pain level postoperative

Secondary trial Id

Secondary data will be gathered using respiratory parameters, delirium, headache, nausea and vomiting, and hemodynamic parameter.

Registration date

2023-02-01, 1401/11/12

Ethics committees

1

Ethics committee

Name of ethics committee
Iraq ministry of health

Street address
Alhaboby street

City
Thi-qar

Postal code
00964

Approval date
2021-09-21, 1400/06/30

Ethics committee reference number
37/2021

Health conditions studied

1

Description of health condition studied
Efficacy of melatonin to patient with caesarian section under spinal anesthesia with ASA I and ASA II

ICD-10 code
F06.4

ICD-10 code description
anxiety

Primary outcomes

1

Description
blood losses and pain level

Timepoint
no

Method of measurement
. The hemoglobin levels before and 12 h after surgery, the mean weight of the materials used in the operation time, and amount of blood suction. Visual pain score and analgesic administration were using to measure level of pain.

Secondary outcomes

1

Description
respiratory parameters, delirium, headache, nausea and vomiting, and hemodynamic parameter and Mother and child status

Timepoint
No

Method of measurement
Used monitor , Apgar score ,

Intervention groups

1

Description
Intervention group: Eighty patients who had been scheduled for cesarean section under spinal anesthesia were enrolled in the study. We randomly allocated them every group has 40 patients, melatonin group (M) and placebo group (P). The dose was given to patient at the night and 90 minutes before the operation (10 mg) sublingually per doses

Category
Treatment - Drugs

2

Description
Control group: Eighty patients who had been scheduled for cesarean section under spinal anesthesia were enrolled in the study. We randomly allocated them every group has 40 patients, melatonin group (M) and placebo group (P). The dose was given to patient at the night and 90 minutes before the operation (10 mg) sublingually per doses

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Bint Alhuda hospital

Full name of responsible person
Iraq ministry of health Bint Al Huda hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Alayen universty

Full name of responsible person
Hussein Jameel Abed

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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
www.alayen.edu.iq

Proportion provided by this source
25

Public or private sector
Private

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
Alayen universty

Full name of responsible person
Hussein Jameel Abed

Position
Iraq - Di-qar

Latest degree
Ph.D.

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

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university of Sousse

Full name of responsible person
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Tunis

Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

primary data include anxiety, sedation, blood loss, postoperative opioid conception, and postoperative pain intensity. Secondary data will be gathered using respiratory parameters, delirium, headache, nausea and vomiting, and hemodynamic parameter. Finally, personal observations and photographs were taken at the study area to supplement the data analysis with valid inputs.

When the data will become available and for how long

we started to collect the data from 1/3/2023 to 30/6/2023

To whom data/document is available

. The selected samples are patients in Bint-Alhuda hospital in Al Nasiriyah included adult women patients of both sexes (18 to 45 years of age) undergoing c/s procedure for which it was necessary to use spinal anaesthesia.

Under which criteria data/document could be used

: age exceeding 18 years, categorized as ASA I or ASA II, pregnancy at a gestational age surpassing 37 weeks, unbroken membranes, scheduled surgical procedures, patient agreement and contentment with study participation, and women with a solitary pregnancy.

From where data/document is obtainable

Bint-Alhuda hospital at the Al-Nasiriyah city of Iraq. Al-Nasiriyah city is in the Governorate of Thiqar, south of Iraq. The city is situated between longitude 31º 08′ E and 31º 01′ E and latitude 46º 18′ N 46º and 08′ N.

What processes are involved for a request to access data/document

After obtaining institutional ethic committee approval with code 37/2021 and patients' informed consent, this prospective randomized double-blind study was conducted in the operating theatre of caesarean sections

Comments

Thank you for giving me the opportunity to register on the site. I hope to receive your valuable comments as soon as possible so that they can be taken into account in order to evaluate the work. I have the utmost respect for you.