Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Different Doses and side effects of Ketamin for Pain Control after Cesarean Section Surgery in Patients with Spinal Anesthesia

Protocol summary

Study aim
Determining the effect of different doses of ketamine on pain control after cesarean section in patients under spinal anesthesia

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 120 patients. Random allocation software was used for randomization.

Settings and conduct
The study will be conducted in Hajar Hospital, and the participants and the statistical consultant will not know which of the study groups the participants are in. After spinal anesthesia, the intervention groups will receive the bolus dose of ketamine immediately after the umbilical cord clamp and the infusion dose until the end of the procedure. The baby's Apgar score will be recorded at 1 and 5 minutes after birth. After cesarean section, the researcher will record the time of the first feeling of pain using Analogue Scale Visual. The time required for pain medication after the completion of spinal anesthesia and the complications will also be recorded.

Participants/Inclusion and exclusion criteria
Conditions for entering the study 1. Having a term pregnancy and ASA class I, II 2. Absence of any underlying diseases 3. Absence of any mental illnesses or mental disorders Conditions for withdrawing from the study 1. Having one of the diseases associated with pregnancy, such as gestational blood pressure or gestational diabetes and fetal problems 2. Allergy to ketamine or similar drugs 3. BMI higher than 30

Intervention groups
The first intervention group will receive 0.25 mg/kg bolus and 0.125 mg/kg continuous infusion during surgery of ketamine. The second intervention group will receive 0.5 mg/kg bolus and then 0.25 mg/kg continuous infusion of ketamine. The control group will also receive normal saline equal to the volume of liquid injected in the intervention groups.

Main outcome variables
pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230417057937N1**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**
Registration date
2023-08-12, 1402/05/21

Registrant information
Name
amin rabiei
Name of organization / entity
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Iran (Islamic Republic of)
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+98 38 3452 3824
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-23, 1402/06/01
Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Different Doses and side effects of Ketamin for Pain Control after Cesarean Section Surgery in Patients with Spinal Anesthesia

Public title
Investigating the effect of ketamine in pain control after cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having a term pregnancy and ASA(American Society of Anesthesiologists) class I, II Participants in the study should refer electively for caesarean section Consent to participate in the study Absence of any underlying diseases Absence of any mental illnesses or mental disorders

Exclusion criteria:
The presence of one of the diseases associated with pregnancy, such as gestational blood pressure or gestational diabetes and fetal problems. Allergy to ketamine or similar drugs BMI above 30

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation of participants to 3 groups will be done by permutation blocks with a size of 40. The Random Allocation software will prepare the randomization list and will be given to a person who does not know the content of the groups' interventions.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to make the study double-blind, the patients will be selected by a person who has no role in examining the patient based on the list of random numbers and the file number will be selected as codes 1, 2, and 3, and the drug and placebo will be injected by the researcher, and the patient will be examined before and It is also performed by the researcher after cesarean section. The patient does not know what group he is in, and the statistical consultant will only know about the studied groups in the form of codes.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences

Street address
Kashani Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8813733424

Approval date
2022-06-08, 1401/03/18

Ethics committee reference number
IR.SKUMS.MED.REC.1401.009

Health conditions studied

1

Description of health condition studied
Post-surgery pain

ICD-10 code
O74.8

ICD-10 code description
Other complications of anaesthesia during labour and delivery

Primary outcomes

1

Description
Comparison of postoperative pain scores in patients receiving intravenous ketamine and the group receiving normal saline

Timepoint
0, 30, 60, 90, 120 minutes and 4, 6, 12, 24 hours after cesarean سثزفهخد

Method of measurement
Analogue Scale Visual

Secondary outcomes

1

Description
Determining the relative frequency of hallucinations in

the group receiving intravenous ketamine

Timepoint

20 minutes after receiving the first dose of medicine

Method of measurement

Based on questions from the patient

2

Description

The time required for pain medication after the completion of spinal anesthesia

Timepoint

The first 24 hours after cesarean section

Method of measurement

Time of drug administration

3

Description

Apgar score of the newborn

Timepoint

The first and fifth minutes after birth

Method of measurement

It includes 5 components: heart rate, respiratory effort, muscle tone, reflex excitability, color

Intervention groups

1

Description

The first intervention group: Ketamine is initially given as a bolus dose of 0.25 mg/kg and then as a continuous infusion of 0.125 mg/kg during the operation.

Category

Treatment - Drugs

2

Description

The second intervention group: Ketamine is initially given as a bolus dose of 0.5 mg/kg and then as a continuous infusion of 0.25 mg/kg during the operation.

Category

Treatment - Drugs

3

Description

Control group: they will receive normal saline injection equal to the volume of liquid injected in the intervention groups.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Azadeh Bahadori

Street address

Hajar hospital, Parastar St.

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Hajar-Hospital@SKUMS.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Raeisi

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elhamraeisi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahre-kord University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Shahre-kord University of Medical Sciences

Full name of responsible person
Amin Rabiei
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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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
Main outcome information
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Only for researchers working in academic and scientific institutes
Under which criteria data/document could be used
to be used in future studies
From where data/document is obtainable
amin rabiei aminrabiei1997@gmail.com
What processes are involved for a request to access data/document
Presenting documents of working in academic and scientific institutions
Comments