Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of low dose Ketamine on postoperative pain after spinal anesthesia in cesarean section

Protocol summary

Summary

The aim of this study was to determine the effect of low dose (0.15 mg/kg) of ketamin on postoperative pain and analgesic consumption after cesarean section. In a randomized double blind clinical trial study, 120 women undergoing elective cesarean section in Tleghani Hospital, Arak were studied. Ketamine (0.15 mgkg-1) or an equal volume of normal saline was given intravenously immediately after initiating spinal anesthesia in the intervention and control group, respectively. Techniques of anesthesia and surgery were the same in both groups. Postoperative pain was assessed by visual analogue scale (VAS) and homodynamic signs, drowsiness of mother and Apgar scores after cesarean, analgesic consumption and first time of analgesic administration were recorded at 5 visits (the first at recovery then every 6 hours).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811173289N1**
Registration date: **2010-08-27, 1389/06/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-08-27, 1389/06/05

Registrant information

Name

Esmail Moshiri

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

dr_moshiri@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2009-10-05, 1388/07/13

Expected recruitment end date

2010-02-11, 1388/11/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low dose Ketamine on postoperative pain after spinal anesthesia in cesarean section

Public title

The effect of low dose Ketamine on postoperative pain after spinal anesthesia in cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: having a term pregnancy, Class ASA I & Π Exclusion Criteria: having a pregnancy problem such as hypertension or GTM in pregnancy or infant problem

Age

No age limit

Gender

Female

Phase

2

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Sardasht, Arak

City
Arak

Postal code

Approval date
empty

Ethics committee reference number
3-64-88

Health conditions studied

1

Description of health condition studied
Delivery by caesarean section, unspecified

ICD-10 code
O82.9

ICD-10 code description
Delivery by caesarean section, unspecified

Primary outcomes

1

Description
The first time that pain killer is necessary

Timepoint
Every 30 min

Method of measurement
visual scale

2

Description
pain severity

Timepoint
Every 30 min

Method of measurement
visual scale

Secondary outcomes

1

Description
mother's pulse rate

Timepoint
Every 30 min

Method of measurement
pulse oxymetery

2

Description
mother's O2 saturation

Timepoint
Every 30 min

Method of measurement
pulse oxymetery

3

Description
mother's blood pressure

Timepoint
Every 30 min

Method of measurement
blood pressure monitor

4

Description
infant's apgar score

Timepoint
Every 30 min

Method of measurement
apgar score pattern

5

Description
mother's sedation

Timepoint
Every 30 min

Method of measurement
ramsay

Intervention groups

1

Description
Spinal anesthesiology was done by anesthesiologist in L3-L4 spaces with spinal needle number G25. In both groups anesthesia was done by xylocaine (5%) 2cc (made by ORIOM Pharm). Xylocaine prescribed 75 - 100 mg according to patient height. Immediately after spinal

anesthesia, ketamine 15 / 0 mg per kg was injected intravenously. Ketamine made by ROPEX MEDICA factory, including 50 mg /cc ketamine.

Category

Prevention

2

Description

Spinal anesthesiology was done by anesthesiologist in L3-L4 spaces with spinal needle number G25. In both groups anesthesia was done by xylocaine (5%) 2cc (made by ORIOM Pharm). Xylocaine prescribed 75 - 100 mg according to patient height. Normal saline was injected as the same volume of ketamine (15/0 mg/ kg).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Esmail Moshiri

Street address

Vali e Asr hospital

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Saeed Ashtyani

Street address

Arak University of Medical Sciences

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Nafiseh Gazerani

Position

M.S. in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Esmail Moshiri

Position

Anesthesiologist

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Other areas of specialty/work

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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