

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparing the analgesic effect of intrathecal Sufentanil with intravenous Acetaminophen in combination with low-dose ketamine on labor pain

Protocol summary

Summary

1.Objectives:The main objective of the study is to compare the analgesic effect of intravenous and intrathecal methods on labor pain.2. Design:Design of study is a randomized single blind. 3.Sample size:120 pregnant women admitted to Kosar Hospital are selected.4.Participants including major eligibility criteria :the inclusion criteria are candidate for natural delivery and being in active phase, and exclusion criteria is the lack of consent of the pregnant mother. 5.Intervention:The study group 1 receives 1g of intravenous acetaminophen with 0.3 mg / kg of ketamine with maintenance dose. The group study 2 undergoes spinal anesthesia by 5 micrograms of sufentanil.6.Main outcome measures:Pain evaluation will be done by using VAS at 10, 20, 30 minutes, and then every 1 hour for 4 hours. The duration of the first and second stage of labor, the fetal heart rate, side effects of the drug, and the first and fifth minutes Apgar score of neonate and respiratory depression in the neonate (if there is) will be recorded.

General information

Acronym

NO

IRCT registration information

IRCT registration number: **IRCT2017082935979N1**

Registration date: **2017-11-14, 1396/08/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-14, 1396/08/23

Registrant information

Name

Mona Koochak Pour

Name of organization / entity

Qazvin University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3323 6375

Email address

m.koochackpour@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the analgesic effect of intrathecal Sufentanil with intravenous Acetaminophen in combination with low-dose ketamine on labor pain

Public title

Comparing the analgesic effect of intrathecal Sufentanil with intravenous Acetaminophen in combination with low-dose Ketamine on labor pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are as follows: o Pregnant women who are candidates for natural delivery and are in the active phase (Cervical dilatation of 5-3 cm); o Pregnant women with no history of physical and psychological illness or

biochemical abnormalities (ASA I class); o Pregnant women who have written and complete consent for the study. Exclusion criteria are as follows: o Dissatisfaction pregnant women; o Mother's preeclampsia and eclampsia; o Insulin-dependent diabetes; o Mother drug abuse history; o Using any analgesic method before entering the study; o History of liver disease; o History or presence of bleeding disorder and coagulation disorders in the mother; o using anticoagulant drugs; o History of mental illness or using antidepressants or anticonvulsants; o Any contraindication for spinal anesthesia; o History of allergic reactions or intolerant to the drugs studied (Sufentanil, acetaminophen and ketamine); o Any significant or severe systemic disease that limits usual and natural activities (such as kidney disease that require dialysis, class 2 heart failure and).

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Qazvin University Of Medical Sciences

Street address

Bahonar Bulvar,Qazvin

City

Qazvin

Postal code

Approval date

2017-04-08, 1396/01/19

Ethics committee reference number

IR.QUMS.REC.1396.4

Health conditions studied

1

Description of health condition studied

Analgesia in Labour

ICD-10 code

O74

ICD-10 code description

Maternal complications arising from the administration of a general or local anaesthetic, analgesic or other sedation during labour and delivery

Primary outcomes

1

Description

Pain

Timepoint

During the intervention

Method of measurement

VAS

Secondary outcomes

1

Description

Age

Timepoint

During Of Intervention

Method of measurement

Year

2

Description

Weight

Timepoint

During Of Intervention

Method of measurement

kilogram

3

Description

First stage of Labour

Timepoint

During Of Intervention

Method of measurement

Minute

4

Description

Neonate APGAR

Timepoint

During Of Intervention

Method of measurement

1to10

5

Description

Blood Pressure

Timepoint

During Of Intervention

Method of measurement

Mm Hg

6

Description

Ephedrine Amount

Timepoint

During Of Intervention

Method of measurement

mg

7

Description

Heart Beat

Timepoint

During Of Intervention

Method of measurement

Beat per minute

8

Description

Nausea and Vomiting

Timepoint

During Of Intervention

Method of measurement

Yes/NO

9

Description

Amount of Natural delivery

Timepoint

During Of Intervention

Method of measurement

Number

10

Description

Petidin Amount

Timepoint

During Of Intervention

Method of measurement

mg

11

Description

Second Stage Of Labour

Timepoint

During Of Intervention

Method of measurement

Minute

Intervention groups

1

Description

Intervention group :1000 mg of intravenous acetaminophen in 100 ml of normal saline will be injected intravenously in 15 minutes with 0.03 mg / kg of ketamine, and the maintenance dose of ketamine is dosed at a rate of 0.3 mg / kg / hour after 30 minutes from the initial dose and after completing the dilatation or in the event of sleepiness and failure to respond to the simple instructions, it's discontinued.

Category

Treatment - Drugs

2

Description

Control group: Spinal anesthesia will be performed in sitting position by needle number 25 and through inter-vertebral spaces of L3-L4 or L4-L5. 5 µg of sufentanil (1 ml) will be used for spinal anesthesia. Immediately after spinal anesthesia, the pregnant woman will be placed in the back and horizontal position, and she is in this situation for 5 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin Kosar Medical Education Center

Full name of responsible person

Dr.Mona Koochak Pour

Street address

Labour Department,kosar Hospital,Taeghani Street,Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research in Qazvin university of medical sciences

Full name of responsible person

Dr.amir peymani

Street address

Vice Chancellor for Research and Technology, Mavedeat Ave, Shahid Beheshti Bulvar, Qazvin

City

Qazvin

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice chancellor for research in 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**

Qazvin University Of Medical Science

Full name of responsible person

Mona Koochak Pour

Position

OBGYN Medical Assistant

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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