Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the analgesic effect of intrathecal Sufentanil with intravenous Acetaminophen in combination with low-dose ketamine onl abor 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 Sceinces

Country

Iran (Islamic Republic of)

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+98 28 3323 6375

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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 onl abor 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
Petedin 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 Sciense
Full name of responsible person
Mona Koochak Pour
Position
OBGYN Medical Assistant
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Person responsible for updating data

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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