

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Ketamine infusion versus spinal analgesia for pain control in painless labor

Protocol summary

Study aim

Aim of this study is comparison of Ketamine infusion versus spinal analgesia for pain control in painless labor

Design

100 patients admitted for normal delivery to Taleghani hospital in Arak are included. Patients are divided into two groups randomly by random numbers table.

Settings and conduct

100 patients admitted for normal delivery to Taleghani hospital in Arak are included. Patients are divided into two groups randomly by random numbers table. This study is clinical trials and double blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: single pregnancy, cephalic embryo, gestational age is equal to or greater than 37 weeks
Exclusion criteria: Sensitivity to ketamine, dissatisfaction

Intervention groups

100 patients admitted for normal delivery to Taleghani hospital in Arak are included. Patients are divided into two groups. In the ketamine group, 0.2 mg of ketamine per kg of maternal weight gain begins with infusion simultaneously with the onset of active phase and continues until the end of delivery and the baby leaves the cervix. In the Spinal Group, patients receive 100 micro gram fentanyl distilled water to 5 milliliter.

Main outcome variables

Pain, motor block level and sensory block

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180614040095N1**

Registration date: **2018-07-28, 1397/05/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-28, 1397/05/06**

Update count: **0**

Registration date

2018-07-28, 1397/05/06

Registrant information

Name

Soumayeh Nikfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

s.nikfar@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2020-05-04, 1399/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Ketamine infusion versus spinal analgesia for pain control in painless labor

Public title

Comparison of Ketamine infusion versus spinal analgesia for pain control in painless labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Single pregnancy Cephalic embryo Gestational age is

equal to or greater than 37 weeks
Exclusion criteria:
Sensitivity to ketamine Dissatisfaction

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

Gender
Female

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with random number in division of groups in two groups A and B. Randomized patients are divided into two groups. Randomized allocation in clinical trial studies refers to the process of dividing participants into different groups randomly. Randomizing gives each participant equal odds for being placed in each of the groups. The candidate patients who enter the study are randomly assigned to the randomly assigned table of randomly assigned to the two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is clinical trial. Outcome evaluator and analyzer are blind (double blind). Outcome evaluator and analyzer don't aware from grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Arak University Of Medical Sciences
Street address
Vice Chancellor For Research, Payambar Azam Complex, Basij Square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Approval date
2018-04-29, 1397/02/09

Ethics committee reference number
IR.ARAKMU.REC.1397.7

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

O75.9

ICD-10 code description

Complication of labour and delivery, unspecified

Primary outcomes

1

Description

Pain

Timepoint

Before, during and after childbirth

Method of measurement

Visual analog pain scale

2

Description

Motor block

Timepoint

Duration delivery

Method of measurement

Bromage scale

3

Description

Sensory block

Timepoint

Duration delivery

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the ketamine group, 0.2 mg of ketamine per kg of maternal weight gain begins with infusion simultaneously with the onset of active phase and continues until the end of delivery and the baby leaves the cervix.

Category

Treatment - Drugs

2

Description

Intervention group: In the Spinal Group, patients receive 100 µg fentanyl distilled water to 5 cc.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Soumayeh Nikfar

Street address

Taleghani hospital, Emam khomeini street

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Email

s.nikfar@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Vice Chancellor For Research, Payambar Azam Complex, Basij Squire, Sardasht, Arak

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arjmandzadegan@arakmu.ac.ir

Web page address

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

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

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Assiatant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Valiasr Hospital, Valiasr Squire, Shahid Shirodi Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Soumayeh Nikfar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

When we publish article in journal.

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Nikfar

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

They have to write letters to the professors and the university

Comments

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Soumayeh Nikfar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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