Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Continous infusion of Remifentanil and Ketamine compared with continous Remifentanil for pain relief in labour

Protocol summary

Summary

The objective of this randomized clinical trial is to compare the effect of remifentanil plus ketamine and remifentanil alone in pain relief during labour. A total of 40 women were recruited and randomly allocated into one of the following groups. The parturients in one receive a bolus dose of remifentanil 25 mg and continous infusion of 0.06 □g/kg/min remifentanil and 0.5 mg/kg/h ketamine for 4 hours (maximum dose of ketamine 2mg/kg) via pump. The parturients in another group receive a bolus dose of remifentanil 25 mg and continous infusion of 0.06 mg/kg/min remifentanil. Pain relief during labor from active phase until labour is measured by using VAS score as the primary outcome. The overall effective analgesia by Likert Scale, arterial blood pressure, heart rate, Spo2, respiratory rate, observer sedation score and fetal heart rate, and presence or absence of nausea and vomiting are recorded and compared between the two groups as secondary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108241952N3**
Registration date: **2011-12-16, 1390/09/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-12-16, 1390/09/25

Registrant information

Name

Ashraf Moini

Name of organization / entity

Tehran University of Medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-01-23, 1389/11/03

Expected recruitment end date

2011-12-30, 1390/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Continous infusion of Remifentanil and Ketamine compared with continous Remifentanil for pain relief in labour

Public title

Pain relief in laour with remifentanil and ketamine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: nulliparous, ASA I, II, gestational age 38-42 weeks in early labour Exclusion criteria: weight less than 50 kg more than 100 kg, candidate to undergo epidural analgesia, multifetus pregnancy, pre-eclampsia, premature labour, allergy to any agent under investigation, history of alcohol or drug abuse, psychiatric disorder

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Ethicc Committee of Arash Hospital

Street address

Arash Women's Hopsital, Baghdarnia Ave., Reslat Hoighway, Tehranpars

City

Tehran

Postal code

Approval date

2010-08-27, 1389/06/05

Ethics committee reference number

677/322/90/د

Health conditions studied

1

Description of health condition studied

pain relief during labour

ICD-10 code

080-0

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes

1

Description

pain relief during labor

Timepoint

from active labor phase (cervical dilation 4-5 cm) until labour

Method of measurement

VAS score

Secondary outcomes

1

Description

heart rate

Timepoint

every 30 minutes

Method of measurement

pulse-oximetry

2

Description

SPO2

Timepoint

every 30 minutes

Method of measurement

pulse-oximetry

3

Description

respiratory rate

Timepoint

every 30 minutes

Method of measurement

visual monitoring

4

Description

fetal heart rate

Timepoint

every 30 minutes

Method of measurement

surface ultrasound

5

Description

present or absent of nausea and vomiting

Timepoint

every time is peresent

Method of measurement

visual monitoring and patient's saying

6

Description

Overall effective analgesia

Timepoint

every 30 minutes after statring analgesia

Method of measurement

VAS score

7

Description
arterial pressure
Timepoint
every 30 minutes after statrting analgesia
Method of measurement
non-invasive arterial presssure monitoring

Intervention groups

1

Description
Intervention group: a bolus dose of remifentanil 25 mg and continous infusion of 0.06 µg/kg/min remifentanil and 0.5 mg/kg/h ketamine for 4 hours (maximum dose of ketamine 2mg/kg) via pump. After four hours if delivery did not happen, we continue only remifentanil with the same dose.
Category
Treatment - Drugs

2

Description
Control group: a bolus dose of remifentanil 25 mg and continous infusion of 0.06 mg/kg/min remifentanil.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Women's Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arash Women's Hospital
Full name of responsible person
Dr Ashraf Moini
Street address
Tehran University of Medical Sciences, Arash women’s Hospital, Rashid Ave., Resalat Highway, Tehranpars. P.O. Box: 1653915981
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arash Women's Hospital
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
Tehran University of Medical Sciences
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Associate Professor
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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