Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Effect of analgesia with intravenous remifentanil versus intravenous pethidine on maternal and neonatal complications and maternal satisfaction with labor during active phase of labor

Protocol summary

Study aim

Effect of analgesia with intravenous remifentanil versus intravenous pethidine on maternal and neonatal complications and maternal satisfaction with labor during active phase of labor

Design

Two arm parallel group randomised trial with blinded patients and outcome assessment

Settings and conduct

The research population was pregnant women referred to normal delivery in the Shahid Ayat Taleghani Hospital. Pregnant women, in the age range of 18 to 45 years old with a gestational age of 37 to 42, cephalalgia, lack of drug addiction, absence of malformation or disease in mother and fetus will be selected.Participants in the study, including a patient, an analyzer who will be analyzed patient information, will be unaware of the study program.

Participants/Inclusion and exclusion criteria

Pregnant women, in the age range of 18 to 45 years old with a gestational age of 37 to 42, cephalalgia, lack of drug addiction, absence of malformation or disease in mother and fetus will be selected, and if they receive any analgesic drug within three hours Before starting the study, they will be excluded from the study.

Intervention groups

Two groups 60,peittidine intravenous analgesia and analgesia will be allocated by the intravenous injection of Remifentanil. In the anesthetic group with pethidine, 25 mg / day of the drug will be diluted with 4 cc distilled water (2-3 minutes). Intervention in the analgesic group with the injection of remi-fentanyl, 10-5 micrograms of remifentanil, will be started by anesthetist for intravenous infusion.

Main outcome variables

The pain in the lower part of the lumbar will be measured once before the intervention and then at 5, 10, 20, 30 minutes after intervention and then every hour by inserting the maternal finger across the ruler in both groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191219045802N1**
Registration date: **2020-07-29, 1399/05/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-29, 1399/05/08**
Update count: **0**

Registration date

2020-07-29, 1399/05/08

Registrant information

Name

leila kafshdooz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3525 7369

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-19, 1399/04/29

Expected recruitment end date

2020-08-19, 1399/05/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of analgesia with intravenous remifentanil versus intravenous pethidine on maternal and neonatal complications and maternal satisfaction with labor during active phase of labor

Public title
Effect of analgesia with intravenous remifentanil versus intravenous pethidine on maternal and neonatal complications and maternal satisfaction with labor during active phase of labor
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women age range of 18 to 45 years old cephalalgia lack of drug addiction absence of malformation or disease in mother and fetus gestational age of 37 to 42
Exclusion criteria:
multiple pregnancy cesarean history
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were allocated into groups,according to simple randomization list.Tables of random numbers will be used.All patients were randomly assigned into tow groups after obtaining the criteria for entering the study randomly into two groups . Pettidine intravenous analgesia and analgesia will be allocated by the intravenous injection of Remifentanil.
Blinding (investigator's opinion)
Single blinded
Blinding description
participants outcome assessors
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Attar neishaboori
City
Tabriz
Province
East Azarbaijan
Postal code
51367
Approval date
2020-04-19, 1399/01/31
Ethics committee reference number
IR.TBZMED.REC.1399.032

Health conditions studied

1

Description of health condition studied
Labour Analgesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pain
Timepoint
The pain in the lower part of the lumbar will be measured once before the intervention and then at 5, 10, 20, 30 minutes after intervention and then every hour by inserting the maternal finger across the ruler in both groups.
Method of measurement
visual analogue pain instrument

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pittidine intravenous analgesia. In the anesthetic group with pethidine, 25 mg / day of the drug will be diluted with 4 cc distilled water (2-3 minutes).
Category
Treatment - Drugs

2

Description
Control group: Remifentanil Intervention in the analgesic group with the injection of remi-fentanyl, 10-5 micrograms of remifentanil, will be started by anesthetist for intravenous infusion.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Ayat ... Taleghani Hospital

Full name of responsible person
Hojjat Pourfathi

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr Samiei

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Dr Hojjat Pourfathi

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Leila Kafshdooz

Position
Researcher

Latest degree
Master

Other areas of specialty/work
Medical Genetics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available