

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Effect of analgesia with intravenous remifentanyl 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 remifentanyl 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, cephalgia, 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, cephalgia, 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 Remifentanyl. 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 remifentanyl, 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

leilakaf@gmail.com

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 remifentanyl 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 remifentanyl 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 cephalgia 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

AgeFrom **18 years** old to **45 years** old**Gender**

Female

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget 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 two groups after obtaining the criteria for entering the study randomly into two groups. Pethidine intravenous analgesia and analgesia will be allocated by the intravenous injection of Remifentanyl.

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: Pethidine 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: Remifentanyl Intervention in the analgesic group with the injection of remi-fentanyl, 10-5 micrograms of remifentanyl, 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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Fax**Email**

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