

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of analgesic effect of remifentanil versus combination of apotel and pethidine on labor pain among mothers candidate for normal vaginal delivery

Protocol summary

Study aim

Comparison of analgesic effect of remifentanil versus combination of apotel and pethidine in labor pain control

Design

In this double-blind clinical trial, phase 2, 100 pregnant women who meet the inclusion criteria are placed in parallel groups in two groups of 50 in a simple random sampling method using a random number table. Patients are explained about the treatment methods, their benefits and side effects and informed consent will be obtained.

Settings and conduct

This study will be performed in Alavi Hospital of Ardabil in mothers who are candidates for natural childbirth in the maternity ward. The study will be double-blind; In this study, placebo and drugs are in the same package and patients and clinical caregivers are unaware of the type of drug received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Over 37 weeks pregnancy, first or second pregnancy, singleton. Non-inclusion criteria: Malpresentation of fetus, macrosomia.

Intervention groups

Intervention group 1: Intravenous Remifentanil 0.05 µg/kg/min (Tofigh Daru Co.) and intravenous injection of placebo (6.7 ml) and 1 ml intramuscular injection of placebo. 2: Intramuscular injection of pethidine (50 mg / ml, Caspian Tamin Co.) and intravenous injection of paracetamol (1 g in 6.7 ml, Caspian Tamin Co.) and 2 ml of placebo intravenous injection.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210101049907N1**

Registration date: **2021-01-30, 1399/11/11**

Registration timing: **prospective**

Last update: **2021-01-30, 1399/11/11**

Update count: **0**

Registration date

2021-01-30, 1399/11/11

Registrant information

Name

Zohre Roshani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3324 8888

Email address

z.roshani@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-10, 1399/12/20

Expected recruitment end date

2021-06-10, 1400/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of remifentanil versus combination of apotel and pethidine on labor pain among

mothers candidate for normal vaginal delivery

Public title

Effect of remifentane and a combination of apotel and Pethidine in reducing labor pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Over 37 weeks pregnancy First or second pregnancy Singleton

Exclusion criteria:

Malpresentation of fetus Macrosomia

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method is a simple randomizing using a table of random numbers, a set of numbers which is completely generated randomly without any specific pattern or order in a table form. Table numbers are read from the left, in a way that even numbers are assigned to intervention A and odd numbers to intervention B. In this way, the researcher touches one of the numbers and moves to the right, then records the numbers and assigns them to different groups. Next, considering the volume of the research sample, aluminum wrapper envelopes are prepared (in order not to clarify the content of the envelopes), each of the random sequences is recorded on a card and placed inside an envelope. To maintain a random sequence, envelopes are numbered in the same way. Finally, the flap of the envelopes are sealed and respectively placed inside a box. To reveal the participants' assigned group, at the beginning of the registration based on the order of eligible participants entry to study, one of the envelopes is opened.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, placebo and drugs are in the same package and participants and clinical caregivers are not aware of the type of medication.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

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Ardabil

Postal code

5615783134

Approval date

2020-07-06, 1399/04/16

Ethics committee reference number

IR.ARUMS.REC.1399.233

Health conditions studied**1****Description of health condition studied**

Labor pain

ICD-10 code

O80

ICD-10 code description

Encounter for full-term uncomplicated delivery

Primary outcomes**1****Description**

Pain

Timepoint

Before analgesic administrations and two times (30 and 60 min) after intervention

Method of measurement

Visual analog scale

Secondary outcomes**1****Description**

Apgar

Timepoint

1 and 5 minutes after birth

Method of measurement

Apgar test

Intervention groups

1

Description

Intervention group: Intravenous Remifentanyl 0.05 µg/kg/min (Tofigh Daru Co.) and intravenous injection of placebo (6.7 ml) and 1 ml intramuscular injection of placebo

Category

Treatment - Drugs

2

Description

Intervention group: Intramuscular injection of pethidine (50 mg / ml, Caspian Tamin Co.) and intravenous injection of paracetamol (1 g in 6.7 ml, Caspian Tamin Co.) and 2 ml of placebo intravenous injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Zohre Roshani

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Alavi Hospital, Moadi street, Ardabil

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Farhad pourfarzi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Zohre Roshani

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

Person responsible for updating data**Contact****Name of organization / entity**

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