Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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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 remifentale 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
City
Ardabi
Province
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 Remifentanil 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
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?
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
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Person responsible for updating data

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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