

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of analgesic effect of paracetamol versus pethidine in labor

Protocol summary

Study aim

Comparison of analgesic effect of paracetamol versus pethidine in labor

Design

In this interventional study, 100 pregnant women who are candidates for natural childbirth will be selected and divided into two groups using block randomization method (n=50 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen.

Settings and conduct

Upon starting the active phase of labor intervention group 1 will receive intravenous Paracetamol 1g/6.7 ml (CaspianTamin Co.) and 1 ml intramuscular placebo injection and intervention group 2 will receive intramuscular Pethidine 50 mg/1 ml (CaspianTamin Co.) and 6.7 ml intravenous placebo injection.

Participants/Inclusion and exclusion criteria

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

Intervention groups

Intervention group 1: Intravenous Paracetamol 1g /6.7 ml (CaspianTamin Co.) and 1 ml intramuscular placebo injection. Intervention group 2: Intramuscular Pethidine 50 mg/1 ml (CaspianTamin Co.) and 6.7 ml intravenous placebo injection.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150808023559N17**

Registration date: **2018-03-24, 1397/01/04**

Registration timing: **prospective**

Last update: **2018-03-24, 1397/01/04**

Update count: **0**

Registration date

2018-03-24, 1397/01/04

Registrant information

Name

Somaieh Matin

Name of organization / entity

Ardabil University of Medicine Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3373 3011

Email address

s.matin@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of paracetamol versus pethidine in labor

Public title

Labor pain relief with paracetamol and pethidine

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

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned randomly by blocking in one of the two specified groups and after selecting the envelope for each patient, before starting the treatment regimen envelope will be opened and based on the protocol, one of two methods will be selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

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

Province

Ardabil

Postal code

5615783134

Approval date

2017-12-31, 1396/10/10

Ethics committee reference number

IR.ARUMS.REC.1396.202

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

Labor pain

ICD-10 code

O80, O84

ICD-10 code description

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 Paracetamol 1g /6.7 ml (CaspianTamin Co.) and 1 ml intramuscular placebo injection

Category

Treatment - Drugs

2**Description**

Intervention group: Intramuscular Pethidine 50 mg/1 ml (CaspianTamin Co.) and 6.7 ml intravenous placebo injection

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alavi Hospital

Full name of responsible person

Farnaz Enamzade

Street address

Alavi Hospital, Moadi street, Ardabil

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Farnaz Enamzade

Position

Gynecology Asisstant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Masoud Entezari

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m.entezari@arums.ac.ir

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Noshin Mobaraki

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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

Ardabil University of Medical Sciences

Full name of responsible person

Farnaz Enamzade

Position

Gynecology Asisstant

Latest degree

Medical doctor

Other areas of specialty/work

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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