

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A clinical trial to compare the effectiveness of acetaminophen and pethidine injection in labor pain reduction in pregnant women

Protocol summary

2017-10-20, 1396/07/28

Summary

Objective: To compare the effectiveness of acetaminophen and pethidine injection in reducing labor pain in pregnant women. Design: A randomized, double-blind, clinical trial based on random number table. Study population: Laboring women requesting pain relief. Inclusion criteria: Term pregnancy, request for pain relief; singleton pregnancy with cephalic presentation; no growth impairment or fetal abnormalities. Exclusion criteria: Medical history of diseases (hepatic, renal, cardiovascular, or respiratory diseases, preeclampsia, diabetes, addiction, allergy to acetaminophen and drug abuse, and G6PD deficiency); need for induction; fetal distress; history of cesarean section. Sample size: 100 cases. Study intervention: The control group will receive 1000 mg of acetaminophen injection in 100 cc of lactate ringer serum during 15 min, and at the same time, injection 5 cc of distilled water in angiocath during 2 min. The intervention group will receive 5 mg injection of pethidine diluted in 5 cc distilled water during 2 min, and simultaneously, 100 cc lactated Ringer's solution will be injected with Micro Drape during 15 minutes. Study outcome: Evaluation and comparison of pain level based on VAS score before and 15 min, 30 min, 1 h, 2 h, 3 h, and 4 h between the intervention and control groups after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100736610N1**

Registration date: **2017-10-20, 1396/07/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Mozhgan Soltani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 5886

Email address

soltanim934@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2018-11-01, 1397/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of acetaminophen and pethidine injection in labor pain reduction in pregnant women

Public title

Comparison of acetaminophen and pethidine in labor pain reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Term pregnancy, request for pain relief; singleton pregnancy with cephalic presentation; no growth impairment or fetal abnormalities. Exclusion criteria: Medical history of diseases (hepatic, renal, cardiovascular, or respiratory diseases, preeclampsia, diabetes, addiction, allergy to acetaminophen and drug abuse, and G6PD deficiency); need for induction; fetal distress; history of cesarean section.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Postal code**Approval date**

2017-11-03, 1396/08/12

Ethics committee reference number

IR.MUMS.sm.REC.1396.95

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

pregnant women

ICD-10 code

Z34

ICD-10 code description

Supervision of normal pregnancy

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

Pain level

Timepoint

Before and 15 min, 30 min, 1 h, 2 h, 3 h, and 4 h after intervention

Method of measurement

VAS score

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: who is receiving 1000 mg of acetaminophen injection in 100 cc of lactate ringer serum during 15 min, and at the same time, injection 5 cc of distilled water in angiocath during 2 min.

Category

Treatment - Drugs

2**Description**

Intervention group: who is receiving 5 mg injection of pethidine diluted in 5 cc distilled water during 2 min, and simultaneously, 100 cc lactated Ringer's solution will be injected with Micro Drape during 15 minutes.

Category

Treatment - Drugs

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

Ghaem Hospital

Full name of responsible person

Mozhgan Soltani

Street address

Ghaem Hospital, Ahmad Abad Street, Dr. Shariati Square

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mozhgan Soltani

Position

Gynaecologist

Other areas of specialty/work

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Mozhgan Soltani

Position

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty