

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effectiveness of acetaminophen and pethidine in the first stage of labor on reducing the pain and maternal complications of primigravid women

Protocol summary

Study aim

Comparison of the efficacy of acetaminophen and pethidine in reducing the pain of the first stage of labor and the maternal complications

Design

Clinical trial with two interventional groups, community based and pragmatic, with parallel groups, one blinded, randomised

Settings and conduct

Prevention, Maternity of Niknafas Hospital, for both groups from the beginning of the active phase of labor (dilatation 4 cm), the administration of the drug (acetaminophen or pethidine) will begin according to the intervention group, the subject and the person evaluating the variables on which individual to which group Allocated, will not be informed.

Participants/Inclusion and exclusion criteria

inclusion criteria: term pregnant women requesting a reduction in labor pain, single with cephalic presentation, No known fetal growth disorder or abnormalities; exclusion criteria: history of medical illness (cardiac, hepatic, renal, pulmonary), preeclampsia, diabetes, drug abuse, acetaminophen and opioid sensitivity, G6PD deficiency), cesarean section history.

Intervention groups

First Intervention group receiving 100 mg acetaminophen in 100 cc serum ringer lactate within 15 minutes and second intervention group receiving 50 mg pethidine within 2 minutes

Main outcome variables

Pain,duration of delivery, maternal complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042595N1**

Registration date: **2019-02-13, 1397/11/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-13, 1397/11/24**

Update count: **0**

Registration date

2019-02-13, 1397/11/24

Registrant information

Name

Masoume Khammar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0038

Email address

masoume.khammar@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-24, 1397/10/03

Expected recruitment end date

2019-12-24, 1398/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of acetaminophen and pethidine in the first stage of labor on reducing the pain and maternal complications of primigravid women

Public title

The effect of acetaminophen and pethidine on reducing the pain of the first stage of labor and its complications in primipara women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Single with cephalic presentation Pregnant women requesting a reduction in labor pain

Exclusion criteria:

Underlying disease(cardiac, hepatic, renal, pulmonary) Preeclampsia Diabetes Drug abuse Sensitization to acetaminophen and opioids G6PD deficiency Cesarean section history

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocking and hiding the assignment of the type of intervention by writing the type of intervention on paper and placing in sealed envelopes that are numbered sequentially.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participant and the person evaluating the variables on which each individual is assigned will not be informed and for hiding the assignment of the type of intervention, the title of the intervention will be written on the paper, and the sealed envelopes are sequentially numbered and placed inside the envelope.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Refsanjan University of Medical Sciences

Street address

Ethics Committee, Rafsanjan University of Medical Sciences, Emam Ali Blvd., Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2018-12-25, 1397/10/04

Ethics committee reference number

IR.RUMS.REC.1397.168

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

Delivery

ICD-10 code

o80

ICD-10 code description

Single spontaneous delivery

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

pain

Timepoint

Before drug administration, 30 minutes, 1, 2, 3 and 4 hours after drug administration

Method of measurement

Visual analog scale(VAS) by graded ruler (0 to 10), which zero is painless and 10 most severe pain states

2**Description**

Maternal complications

Timepoint

From the time of drug injection to 4 hours after delivery

Method of measurement

Nausea, vomiting, drowsiness, respiratory depression

3**Description**

Duration of the first stage of labor

Timepoint

Distilation time of 4 cm to complete dilatation

Method of measurement

minute

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Acetaminophen receptor, 100 mg of acetaminophen in 100 cc serum ringer lactate within 15 minutes

Category

Prevention

2

Description

Second Intervention group: Pethidine, 50 mg pethidine within 2 minutes

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Maternity of Niknafas hospital

Full name of responsible person

Masoume Khammar

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Niknafas Hospital, Shohada St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Ali Ansari

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Masoume Khammar

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

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

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Province**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

Not applicable

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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available