Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect pethidine, paracetamol and their combination on the reduction of labor pain and the level of satisfaction of primiparous women

Protocol summary

Study aim
To assess the effect of pethidine, paracetamol and their combination on the reduction of labor pain and the level of satisfaction of primiparous women

Design
This is a double-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Fatemieh Hospital in Hamadan city on 111 eligible primiparous women. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 40 years Term pregnancy A singleton with a cephalic display Cervical dilatation 4 cm Pregnant women undergoing induction of labor with oxytocin Exclusion criteria: Analgesic consumption in the last 24 hours Preeclampsia and eclampsia Severe obesity Intrauterine fetal death Fetal abnormalities

Intervention groups
Intervention group 1: Infusion of one gr of paracetamol plus 100 ml of normal saline over 20 minutes
Intervention group 2: Infusion of 25 mg of pethidine plus 100 ml of normal saline over 20 minutes Intervention group 3: Infusion of one gr of paracetamol and 25 mg of pethidine plus 100 ml of normal saline over 20 minutes

Main outcome variables
Primary outcome: Labor pain intensity The level of satisfaction Secondary outcome: Side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N455**
Registration date: **2022-12-29, 1401/10/08**
Registration timing: **prospective**

Last update: **2022-12-29, 1401/10/08**
Update count: **0**

Registration date
2022-12-29, 1401/10/08

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect pethidine, paracetamol and their combination on the reduction of labor pain and the level of satisfaction of primiparous women

Public title
Comparison of the effect pethidine, paracetamol and their combination on the reduction of labor pain and the level of satisfaction of primiparous women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 40 years Term pregnancy A singleton with a cephalic display Cervical dilatation 4 cm Pregnant women undergoing induction of labor with oxytocin
Exclusion criteria:
Analgesic consumption in the last 24 hours Preeclampsia and eclampsia Severe obesity Intrauterine fetal death Fetal abnormalities
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **111**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare three sheets of paper, writing on one sheet the name of the intervention 1 and on another sheets the name of the intervention 2 and on the third sheet the name of the intervention 3. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The three paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Hamadan
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Hamadan
Postal code
6517838695
Approval date
2022-09-10, 1401/06/19
Ethics committee reference number
IR.UMSHA.REC.1401.509

Health conditions studied

1

Description of health condition studied
Labor pain
ICD-10 code
O75.0
ICD-10 code description
Maternal distress during labor and delivery

Primary outcomes

1

Description
Labor pain intensity
Timepoint
In the first and fifth minutes after delivery
Method of measurement
Using visual analog scale (VAS)

2

Description
The level of satisfaction
Timepoint
After the third stage of labor
Method of measurement
Using McKay's satisfaction questionnaire

Secondary outcomes

1

Description
Side effects (nausea, vomiting, maternal tachycardia, respiratory depression, drowsiness, itching)

Timepoint
In the first, second and third stage of labor
Method of measurement
With clinical examination and history taking

Intervention groups

1

Description
Intervention group 1: Infusion of one gr of paracetamol plus 100 ml of normal saline over 20 minutes
Category
Treatment - Drugs

2

Description
Intervention group 2: Infusion of 25 mg of pethidine plus 100 ml of normal saline over 20 minutes
Category
Treatment - Drugs

3

Description
Intervention group 3: Infusion of one gr of paracetamol and 25 mg of pethidine plus 100 ml of normal saline over 20 minutes
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital in Hamadan city
Full name of responsible person
Dr Hamideh Parsapour
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Dr Hamideh Parsapour
Position
Gynecologist
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Dr. Jalal Poorolajal

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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