# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Jul 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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**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
**City**
Hamadan
**Province**
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
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Fatemieh Hospital, Pasdaran Ave.
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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**
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**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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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