

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Effect of Pethedin on duration of labor and type of delivery in nulliparous women

#### Protocol summary

##### Summary

Pethidine increases the contraction of the uterus and possibly accelerate the delivery. The purpose of this study was evaluation the effect of Pethedin on duration of labor and type of delivery in nulliparous women. Material and Methods: In a double blind randomized controlled trial 90 nulliparous women participated in the study. After accurate determination of pregnancy age, participants were classified into two groups Pethedine and Placebo (Normal Saline) . The first group (Pethedine group=45 cases) received 50 mg Pethedin Intra Muscular. In the Placebo group (Normal Saline=45 cases) , an equal volume of Normal Saline was prescribed Intra Venous. The mean duration first and second stages, type of delivery and Apgar scour was recorded

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201407016575N5**  
Registration date: **2015-02-15, 1393/11/26**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-02-15, 1393/11/26

##### Registrant information

###### Name

Ashraf Direkvand-Moghadam

###### Name of organization / entity

Ilam University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 84 3222 7134

##### Email address

direkvand-a@medilam.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ilam University of Medical Sciences

##### Expected recruitment start date

2013-04-14, 1392/01/25

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Pethedin on duration of labor and type of delivery in nulliparous women

##### Public title

Effect of Pethedin on duration of labor and type of delivery in nulliparous women

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria:18-35 years of old; nulliparous; singleton pregnancy; gestational age 38-40; without CPD; optimal care during pregnancy; blood pressure less than 140/90 mmHg; pulse 60-110; Body Mass Index 19/8-26 (kg/m) before pregnancy; intact of membrane; estimated fetal weight less than 4000 grams; exclusion criteria: Polyhydramnios; abnormal presentation; Preeclampsia; history of medical problems during and before pregnancy such as Asthma; Cardiovascular and Metabolic disease at the admission time

##### Age

From **18 years** old to **35 years** old

##### Gender

Female

### Phase

2-3

### Groups that have been masked

No information

### Sample size

Target sample size: 90

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ilam University of Medical Sciences

##### Street address

Ilam University of Medical Sciences

##### City

Ilam

##### Postal code

#### Approval date

2010-08-20, 1389/05/29

#### Ethics committee reference number

(EC/91/H/102)

## Health conditions studied

### 1

#### Description of health condition studied

The relationship between Pethedin with the duration of labor and type of delivery in nulliparous women

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Duration of labor in nulliparus women

#### Timepoint

Start of admission to delivery

#### Method of measurement

Duration of labor according to minute

### 2

#### Description

Type of delivery in nulliparous women

#### Timepoint

Start of admission to delivery

#### Method of measurement

Divided into two groups normal vaginal deliveries and cesarean section

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The Pethedin group received 50 mg Pethedin Intra Muscular.

#### Category

Treatment - Drugs

### 2

#### Description

The Placebo group received an equal volume of Normal Saline Intra Venous.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mustafa Khomeini hospital, Ilam University of Medical Sciences

##### Full name of responsible person

Ashraf Direkvand-Moghadam

##### Street address

Ilam University of Medical Sciences

##### City

Ilam

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ilam University of Medical Sciences

##### Full name of responsible person

Dr Iraj Pakzad

##### Street address

Ilam University of Medical Sciences

##### City

Ilam

#### Grant name

#### Grant code / Reference number

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

Yes

**Title of funding source**

Ilam 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**

Ilam University of Medical Sciences

**Full name of responsible person**

Ashraf Direkvand-Moghadam

**Position**

MSc of Midwifery

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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*