

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

### Comparison of the prophylactic effect of Dexamethasone and Ondansetron versus placebo on pruritus due to intrathecal Sufentanil in painless labor: a double blind randomized clinical trial

#### Protocol summary

2017-10-02, 1396/07/10

##### Summary

Objectives: To compare the prophylactic effect of Dexamethasone and Ondansetron versus placebo on pruritus due to intrathecal Sufentanil in painless labor. Design: A double blind randomized clinical trial. Setting and conduct: The eligible pregnant women who will refer to Fatemeh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 45 years; pregnant woman; prim gravida; gestational age of 30 to 40 weeks; enter active phase of labor. Exclusion criteria: Need to emergency cesarean section; sensitivity to Ondansetron or Dexamethasone. Intervention group 1: Intravenous injection of 2 ml Ondansetron (4 mg) single dose before labor. Intervention group 2: Intravenous injection of 2 ml Dexamethasone (8 mg) single dose before labor. Control group: Intravenous injection of 2 ml distilled water single dose before labor. Primary outcome: Assessing pruritus every 15 minutes until labor using Visual Analog Scale (VAS). Randomization: The patients will be randomly assigned to the intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of medication. The physician who will examine the patients will not be aware of the medication. Therefore, the trial will be run as double blind.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201709249014N189**  
Registration date: **2017-10-02, 1396/07/10**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellor for Research and Technology, Hamadan  
University of Medical Sciences

##### Expected recruitment start date

2016-12-30, 1395/10/10

##### Expected recruitment end date

2017-08-21, 1396/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the prophylactic effect of Dexamethasone and Ondansetron versus placebo on pruritus due to intrathecal Sufentanil in painless labor: a double blind randomized clinical trial

##### Public title

Comparison of the prophylactic effect of Dexamethasone

and Ondansetron versus placebo on pruritus due to intrathecal Sufentanil in painless labor

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
Inclusion criteria: Age of 18 to 45 years; pregnant woman; prim gravida; gestational age of 30 to 40 weeks; enter active phase of labor. Exclusion criteria: Need to emergency cesarean section; sensitivity to Ondansetron or Dexamethasone.

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Female

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **63**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**  
Randomization: The patients will be randomly assigned to the intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of medication. The physician who will examine the patients will not be aware of the medication. Therefore, the trial will be run as double blind.

## 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 the Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**  
Hamadan

**Postal code**

**Approval date**  
2016-12-24, 1395/10/04

**Ethics committee reference number**  
IR.UMSHA.REC.1395.421

## Health conditions studied

### 1

**Description of health condition studied**  
Pruritus

**ICD-10 code**  
L29

**ICD-10 code description**  
Pruritus

## Primary outcomes

### 1

**Description**  
Assessing pruritus

**Timepoint**  
every 15 minutes until labor

**Method of measurement**  
Using Visual Analog Scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**  
Intervention group 1: Intravenous injection of 2 ml Ondansetron (4 mg) single dose before labor.

**Category**  
Treatment - Drugs

### 2

**Description**  
Intervention group 2: Intravenous injection of 2 ml Dexamethasone (8 mg) single dose before labor.

**Category**  
Treatment - Drugs

### 3

**Description**  
Control group: Intravenous injection of 2 ml distilled water single dose before labor.

**Category**  
Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**  
Fatemieh Hospital

**Full name of responsible person**  
Zeinab Ghanbari

**Street address**

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**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 and Technology, Hamadan  
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**

Fatemieh Hospital

**Full name of responsible person**

Zeinab Ghanbari

**Position**

Medical Student

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific

## inquiries

**Contact**

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Fatemieh Hospital

**Full name of responsible person**

Dr Pooran Hajian

**Position**

Anesthesiologist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

**Other areas of specialty/work**

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## 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*