

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

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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

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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

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

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Person responsible for updating data

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Name of organization / entity

Department of Epidemiology

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Dr Jalal Poorolajal

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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