

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

comparison between prophylactic effect of ondansetron versus dexamethason in reducing of opioid induced pruritus in labor analgesia with intratechal sufentanil

Protocol summary

Summary

After approval by the Ethics & Research committee of Hamadan University of Medical Sciences and obtaining written informed consent, 61 patients classified as ASA I (18–45 years) with gestational age 36–42 weeks who were scheduled for laboe under regional analgesia participated in this double blinded clinical trial. Patients were excluded for the following reasons: preeclampsia, chronic hypertension, diabetes, hepatic or renal disorders, allergy to drugs in the study, contraindication of neuraxial anesthesia,, mother addiction and drug abuse and any unexpected accident that need to cesarean section and privious history of pruritus or allergy to study drug . Before induction of spinal analgesia, baseline standard monitoring was recorded in a supine position by automatic monitoring (Novin S 1800, Saadat model). Spinal analgesia was administered by a 25 gauge Quincke needle (Mekon Medical devices Co. Shanghai China) at the L3-L4 inters pace, parallel to the dural fiber, while the patient was in the sitting position. Spinal analgesia consisted of 10 µg (2 ml) Sufentanil (Sufiject Aburaihan Co. Iran)administered in 12 sec. Patients were randomly allocated using opaque envelopes (block randomization with a block size of six) into three groups: groups1 and 2, in which the patients received 4mg ondansetron or 8 mg dexamethasone ,before induction of spinal analgesia, and group 0, in which the patients recieved normal salin as placebo. . To blinding the study, one anesthesiologist administered the spinal analgesia and randomized the patients, and another assistant performed drug preparation and injection. Systolic blood pressure (SBP), heart rate (HR), mean arterial blood pressure (MAP) and O2 saturation (SpO2) were recorded 1 min before (as baseline), and 5, 10, 15min after induction of analgesia, and there after in 15 minutes interval through the end of labor.scratching was observed and severity of pruritus was assessed by

visual analogue scale of pruritus in above time intervals.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052328010N1**

Registration date: **2017-10-05, 1396/07/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-05, 1396/07/13

Registrant information

Name

Pouran Hajian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0312

Email address

hajian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2016-06-19, 1395/03/30

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 between prophylactic effect of ondansetron versus dexamethason in reducing of opioid induced pruritus in labor analgesia with intratechal sufentanil

Public title
Prophylaxis of opioid induced pruritus in labor analgesia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: parturient aged 18-45 and ASA I with gestational age 36-42 weeks that candidates for labor under regional analgesia. Exclusion criteria: preeclampsia; chronic hypertension; diabetes mellitus; allergy to drugs in the study; contraindication of neuraxial anesthesia; mother addiction and drug abuse and any unexpected accident that need for cesarean section; previous history of itching and allergy.

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Committee of Ethics in Research, Hamadan University of Medical Sciences

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Street, Hamadan

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
Intra echal Opioid Induced Pruritus

ICD-10 code
O74.6

ICD-10 code description
Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes

1

Description
Intratechal opioid induced pruritus

Timepoint
just after spinal anesthesia, 5, 10, 15 min later then every 15 mint to 90 min

Method of measurement
Pruritus was asses by observe the scraching and by Visual Analouge Scale of pruritus every 5 Minute for 15 minute and every 15 mnutes untile 90 min

Secondary outcomes

1

Description
Other complication of spinal anesthesia: nausea & vomitting, hypotension

Timepoint
After spinal anesthesia untile the end of labor or to 90 min after spinal anesthesia

Method of measurement
Blood pressure was measured with automatic blood pressure device and hypotension was defined as more than 20% decrease of BP compared to baseline, and observation of any retching or explosion Of gastric content

Intervention groups

1

Description
Intervention 1: before performing intratechal opioid injection, 2cc Ondansetrone was injected intravenously

Category
Treatment - Drugs

2

Description

Control group: before performing intratechal opioid, 2cc distilled water was injected intravenously

Category

Placebo

3

Description

Intervention 2: before performing lintra techal opioid injection, 2cc Dexamethasone was injected intravenously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh hospital

Full name of responsible person

Pouran Hajian

Street address

Pasdaran Street, Shariati square

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

Saiid Bashirian

Street address

Hamadan University of Medical Science, Shahid
Fahmideh street, Hamadan

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

Endometrium and Endometriosis Research Center

Full name of responsible person

Pouran Hajian M.D

Position

Assistant Professor of Anesthesiology And Pain

Other areas of specialty/work

Street address

Anesthesiology Department, Besat hospital, Shahid
Motahari Blvd, Resalat Square, Hamadan

City

Hamadan

Postal code

Phone

+98 81 3838 3090

Fax

Email

hajian@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Endometrium and Endometriosis Research center &
Hamadan University of Medical Sciences

Full name of responsible person

Pouran Hajian M.D

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

Street address

Anesthesiology Department, Besat hospital, Shahid
Motahari Blvd, Resalat Square, Hamadan

City

Hamadan

Postal code

Phone

+98 81 3264 0049

Fax

Email

hajian@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Endometrium and Endometriosis Research
Center, Hamadan, Hamadan University of Medical
Sciences

Full name of responsible person

Pouran Hajian M.D

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

Street address

Anesthesiology Department, Besat hospital, Shahid

Motahari Blvd, Resalat Square, Hamadan

City

Hamadan

Postal code

Phone

+98 81 3838 0312

Fax

Email

pooranhajian567@yahoo.com

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