Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparing the Prophylactic Effect of Intravenous Ondansetron And Granisetron On Pruritus after Intrathecal Morphine in Elective Cesarean Surgery

Protocol summary

Summary

The appearance of pruritus is frequent after use of intrathecal morphine, especially after cesarean section. This pruritus is often difficult to treat and responds poorly to conventional treatments to comparing the prophylactic effect of intravenous ondansetron and granisetron on pruritus after intrathecal morphine in elective cesarean surgery, in randomized, double-blind clinical study 90 pregnant women that candidate for elective caesarean section with intrathecal morphine entered the study. Patients were divided into three groups, and the same procedure was performed to spinal anesthesia. Before spinal anesthesia group one received 8 mg ondansetron, group two received 3mg granisetron and group 3 received 4mg normal salin. After operative, pruritus were assessed with a visual analog scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092219252N1**
Registration date: **2014-10-05, 1393/07/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-10-05, 1393/07/13

Registrant information

Name

Sara Kohani

Name of organization / entity

Ahwaz Jondishapur University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jondishapour University of Medical Sciences

Expected recruitment start date

2014-03-12, 1392/12/21

Expected recruitment end date

2014-07-12, 1393/04/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Prophylactic Effect of Intravenous Ondansetron And Granisetron On Pruritus after Intrathecal Morphine in Elective Cesarean Surgery

Public title

Effect of Ondansetron and Granisetron For The Prevention Of Pruritus In Patients Undergoing Cesarean Section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Women undergoing elective cesarean section with spinal anesthesia. Exclusion criteria: Drug addiction; history of allergy to ondansetron, granisetron and morphine; electrolyte abnormalities; history of pruritic skin diseases and other systemic diseases.

Age

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

Gender
Female

Phase
N/A
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
Ethics Committee of Ahwaz Jondishapour University Of Medical Sciences
Street address
Ethics Committee of Ahwaz Jondishapour University Of Medical Sciences, Golestan Blvd., Ahwaz
City
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Postal code
Approval date
2014-05-07, 1393/02/17
Ethics committee reference number
ajums.REC.1393.176

Health conditions studied

1

Description of health condition studied
Pruritus
ICD-10 code
L29.9
ICD-10 code description
Pruritus, unspecified

Primary outcomes

1

Description
pruritus
Timepoint
3, 6 and 18 hour after intrathecal morphine
Method of measurement
visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Group1: injection 8 mg ondansetron before intrathecal morphine
Category
Prevention

2

Description
Group2: injection 3mg granisetron before intrathecal morphine
Category
Prevention

3

Description
Group3: injection 4mg normal salin before intrathecal morphine
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini Hospital
Full name of responsible person
Sara Kohani
Street address
Emam Khomeini Hospital, Shahid Ahvazian, Ahvaz
City
Ahwaz

2

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Sara Kohani
Street address
Razi Hospital, Felestin St, Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahwaz Jondishapour University of Medical Sciences
Full name of responsible person
Reza Malekzadeh
Street address
Ahwaz Jondishapour University of Medical Sciences, Golestan BLvd., Ahwaz
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Ahwaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahwaz Jondishapour 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
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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