Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of oral meloxicam with paracetamol and sufentanil pain pump in analgesia after cesarean section

Protocol summary

Study aim
Effectiveness of oral administration of meloxicam with pain pump containing paracetamol and sufentanil on analgesia after cesarean section
Design
The control group consisted of patients receiving placebo in the form of oral meloxicam at a dose of 7.5 mg two times before the onset of the spinal anesthesia and 12 hours later with a pain control pump
Settings and conduct
Ali ebn Abi Talib hospital in Zahedan, not blinded clinical trial controlled with placebo, randomized blocking
Participants/Inclusion and exclusion criteria
Inclusion criteria: age range 18 to 38 years; term pregnancy; elective cesarean; ASA class one and two. Exclusion criteria: drug abuse; bleeding disorders; severe psychiatric disorders; body mass index higher than 35; preeclampsia
Intervention groups
The intervention group included patients receiving meloxicam tablets (Hexal, Germany) orally at a dose of 7.5 mg two times before the onset of spinal anesthesia and 12 hours later with a pain control pump
Main outcome variables
Pain intensity; need for analgesic

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180206038648N1**
Registration date: **2018-02-23, 1396/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-23, 1396/12/04**
Update count: **0**
Registration date
2018-02-23, 1396/12/04

Registrant information
Name
Saman Nasrollahi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-06-26, 1396/04/05
Expected recruitment end date
2018-06-26, 1397/04/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of oral meloxicam with paracetamol and sufentanil pain pump in analgesia after cesarean section

Public title
Efficacy of oral meloxicam in analgesia after cesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Elective cesarean section Term pregnancy ASA Class I & II

Exclusion criteria:
Drug abuse Bleeding disorders Severe psychiatric disorders Body mass index higher than 35 Preeclampsia

Age
From **18 years** old to **38 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Blocks

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences

Street address
Ali-ebn Abi Talib Hospital, Salamat Blvd., Daneshgah Ave., Zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743111

Approval date
2017-06-25, 1396/04/04

Ethics committee reference number
IR.ZAUMS.REC.1396. 74

Health conditions studied

1

Description of health condition studied
Cesarean section

ICD-10 code
O82.9

ICD-10 code description
Delivery by caesarean section, unspecified

Primary outcomes

1

Description
Pain intensity

Timepoint
6,12, and 24 hours after surgery

Method of measurement
VAS (Vision Scale)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: administration of the meloxicam tablet (Hexal, Germany) orally at a dose of 7.5 mg two times before the onset of the spinal anesthesia and 12 hours later

Category
Treatment - Drugs

2

Description
Control group: administration of a meloxicam-like tablet placebo two times before the onset of spinal anesthesia and 12 hours later.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali-ebn Abi Talib Hospital

Full name of responsible person
Saman Nasrollahi

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Sponsors / Funding sources

1

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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
Zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Anesthesia resident
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available