

# 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

2018-02-23, 1396/12/04

#### 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

#### Registrant information

##### Name

Saman Nasrollahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3329 5778

##### Email address

dr.nasrollahi@zaums.ac.ir

#### 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

**Street address**

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

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743111

**Phone**

+98 54 3329 5570

**Email**

dr.nasrollahi@zaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tahri

**Street address**

Hesabi Sq., Daneshgah Ave., Zahedan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

+98 54 3329 5744

**Email**

dr.taheri@zaums.ac.ir

**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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Saman Nasrollahi

**Position**

Anesthesia resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

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

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743111

**Phone**

+98 54 3329 5570

**Email**

dr.nasrollahi@zaums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr Jamshid Ordoni Aval

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Ali eb abi Talib Hospital, Salamat Blvd., Daneshgah Ave., Zahedan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743111

**Phone**

+98 54 3329 5570

**Email**

dr.ordoniaval@zaums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Saman Nasrollahi

**Position**

Anesthesia resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

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

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743111

**Phone**

+98 54 3329 5570

**Email**

dr.nasrollahi@zaums.ac.ir

## **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