

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparison of Mefenamic Acid Effect in combination with Paracetamol and Ketorolac containing Pain Pump on Analgesia after cesarean section

#### Protocol summary

##### Study aim

Comparison of Mefenamic Acid effect in Combination with Paracetamol and Ketorolac containing pain pump on analgesia after cesarean section

##### Design

Phase 2-3 clinical trial with control group; sample size of 60; community based and pragmatic; with parallel, not-blinded, randomized with random blocks (6 blocks of 10).

##### Settings and conduct

Supportive cares; Ali-ebn Abi-Talib hospital in Zahedan

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: elective cesarean section; first or repeated caesarean section; term pregnancy; ASA Class I & II; spinal anesthesia Exclusion criteria: drug abuse; hemorrhagic disorders; severe psychiatric disorders; gastrointestinal disorders; Grade 2 obesity (with a BMI higher than 35); general anesthesia; preeclampsia; the presence of adhesion during surgery; prolongation of operation; massive intraoperative bleeding.

##### Intervention groups

The intervention group (M) will receive mefenamic acid capsule 250 mg orally two times before the onset of the spinal anesthesia and 6 hours later with an intravenous PCA pain control pump containing 35 mg per kg paracetamol and one milligram per kilogram of ketorolac at a rate of injection of 4 ml per hour. Control group (C) will receive placebo with same shape of mefenamic acid two times before the onset of the spinal anesthesia and 6 hours later with an intravenous PCA pain control pump containing 35 mg per kg paracetamol and one milligram per kilogram of ketorolac at a rate of injection of 4 ml per hour.

##### Main outcome variables

Pain intensity

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180523039812N1**

Registration date: **2018-06-18, 1397/03/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-18, 1397/03/28**

Update count: **0**

#### Registration date

2018-06-18, 1397/03/28

#### Registrant information

##### Name

Iman Abili

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3329 5721

##### Email address

dr.abili@zaums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2017-06-12, 1396/03/22

#### Expected recruitment end date

2018-07-13, 1397/04/22

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of Mefenamic Acid Effect in combination with Paracetamol and Ketorolac containing Pain Pump on Analgesia after cesarean section

**Public title**

Effect of mefenamic acid on analgesia after cesarean section

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Elective cesarean section First or repeated caesarean section Term pregnancy ASA Class I & II Spinal anesthesia

**Exclusion criteria:**

Substance abuse bleeding disorders Severe psychiatric disorders Gastrointestinal disorders Obesity grade 2 (with a BMI greater than 35) General anesthesia Preeclampsia The presence of adhesion during surgery Prolongation of operation Massive bleeding during surgery

**Age**

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

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Blocks; Individuals; Random numbers

**Blinding (investigator's opinion)**

Not 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 Zahedan University of Medical Sciences

**Street address**

Campus of the University of Medical Sciences,  
Dr.Hesabi Sq., Daneshgah Ave., Zahedan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Approval date**

2017-06-12, 1396/03/22

**Ethics committee reference number**

IR.ZAUMS.REC.1396.55

**Health conditions studied****1****Description of health condition studied**

Post-caesarean section analgesia

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Pain intensity

**Timepoint**

6, 12 and 24 hours after surgery

**Method of measurement**

Visual Analogue Scale

**2****Description**

Sedation

**Timepoint**

6, 12 and 24 hours after surgery

**Method of measurement**

Ramsay sedation scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: receiving Mefenamic acid capsule (al-Hawi, Iran) orally 250 mg two times before the start of the spinal anesthesia and 6 hours later with an intravenous PCA pain control pump containing 35 mg per kg paracetamol and one milligram per kilogram of ketorolac at a rate of injection of 4 ml per hour.

**Category**

Treatment - Drugs

**2****Description**

Control group: receiving placebo with same shape of Mefenamic acid two times before the start of the spinal anesthesia and 6 hours later with an intravenous PCA pain control pump containing 35 mg per kg paracetamol and one milligram per kilogram of ketorolac at a rate of injection of 4 ml per hour.

**Category**

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ali-ebn Abi-Talib Hospital-Zahedan

**Full name of responsible person**

Iman Abili

**Street address**

Ali-eb Abi-Talib Hospital, Salamat Highway, Khalijefars Blvd.

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743111

**Phone**

+98 54 3329 5570

**Email**

dr.abili@zaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mohsen Taheri

**Street address**

Campus of the University of Medical Sciences,  
Dr.Hesabi Sq., Daneshgah Ave., Zahedan

**City**

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**Province**

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**Postal code**

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**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**

Iman Abili

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

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## Person responsible for scientific inquiries

#### Contact

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Zahedan University of Medical Sciences

**Full name of responsible person**

Iman Abili

**Position**

Resident

**Latest degree**

Medical doctor

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## Person responsible for updating data

#### Contact

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Zahedan University of Medical Sciences

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Iman Abili

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Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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Dr.abili@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