Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Ketorulac 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.

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9816743111

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+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

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+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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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