Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The Effect of Paracetamol versus Ketorolac on Postoperative Pain of Cesarean Section

Protocol summary

Study aim
Determine and compare the effect of paracetamol and ketorolac on pain reduction after cesarean section

Design
Clinical trial has a control group, supportive and community-oriented, and pragmatic, with parallel, blind, and randomized groups which there was 125 of them considered as sample size

Settings and conduct
In group A, 1000 mg of paracetamol is injected and in group B, 30 mg of ketorolac ampoule is injected intravenously in at least 15 seconds. the medications package are similar and are identified by codes and then the pain score is recorded at the time of injection and after 6 hours, 12 hours, and 24 hours after the injection.

Participants/Inclusion and exclusion criteria
The inclusion criteria of the study are first parity women aged 20 to 45 years with the weight between 60 and 80 kg, indicating the termination of pregnancy by cesarean in obstetrics and gynecology ward of Imam Ali clinic of Zahedan in 1396. The exclusion criteria are having chronic disorders of pregnancy

Intervention groups
In group A, parastamol In the time of zero, 1000 mg is injected. Each ampoule of 7.6 mg paracetamol (appendix) contains 1000 mg of acetaminophen, which dissolves each ampoule in 100 ml of normal saline and is injected intravenously within 15 minutes. The pain score is recorded at the injection time of 24, 12, 6, 0, and for every 8 hours 1000 mg of this drug is injected to reach the 24-hour period. Group B, 30 mg intravenous injection of ketorolac is injected in at least 15 seconds, and then the pain score is recorded at the injection time of 24,12,6,0.

Main outcome variables
pain scale; satisfaction; adverse effect; time of surgery ;

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180425039418N3**
Registration date: **2018-12-29, 1397/10/08**
Registration timing: **retrospective**

Last update: **2018-12-29, 1397/10/08**
Update count: **0**

Registration date
2018-12-29, 1397/10/08

Registrant information
Name
mohammad Ghena'at Pisheh Sanani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 54 3343 1227
Email address
mohammad.ghenaat71@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-20, 1396/12/01
Expected recruitment end date
2018-05-21, 1397/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The Effect of Paracetamol versus Ketorolac on Postoperative Pain of Cesarean Section

Public title
The Effect of Paracetamol versus Ketorolac on Postoperative Pain of Cesarean Section
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All women who are at the term gestational age with the first pregnancy who are candidates for termination of pregnancy by elective cesarean section
Exclusion criteria:
The mothers who have the chronic disorders such as Lupus erythematosus
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
The first parity pregnant women who were candidates for elective cesarean were randomly assigned to two groups one of which was treated with paracetamol and the other one was treated with ketorolac.
Blinding (investigator's opinion)
Single blinded
Blinding description
Paracetamol and Ketorolac drug packs are in homogeneous units so that the names of the medications are hidden and only the code is written on the drug units and the researcher is aware of the drug codes and will only give the nurse the name of the medicine in the event of an emergency situation
Placebo
Not 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
Medical Sciences Campus, Doctor Hesabi Square,
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2017-05-04, 1396/02/14
Ethics committee reference number
IR.ZAUMS.REC.1396.142

Health conditions studied

1

Description of health condition studied
post-Cesarean pain
ICD-10 code
O82
ICD-10 code description
Encounter for cesarean delivery without indication

Primary outcomes

1

Description
post-cesarean pain
Timepoint
the first time of pain sensation after surgery, 6 hours after the surgery, 12 hours after surgery, 24 hours after surgery
Method of measurement
VAS visual acuity scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Group A paracetamol is injected at a time of zero 1000 mg. Each ampoule of 7.6 mg paracetamol (appendix) contains 1000 mg of acetaminophen, which dissolves each ampoule in 100 ml of normal saline and is injected intravenously within 15 minutes. The pain score is recorded at the injection time of 24, 12, 6, 0, and for every 8 hours 1000 mg of this drug is injected to reach the 24-hour period.
Category
Treatment - Drugs

2

Description
Intervention group 2: Group B, 30 mg intravenous injection of ketorolac is injected in at least 15 seconds,

and then the pain score is recorded at the injection time of 24,12,6,0. At the end, each patient is evaluated for visual signs and visual inspection criteria at 0, 6, 12 and 24 hours after medication administration and evaluated and compared using the VAS form. Regarding ethical considerations and respect for patients' rights. Despite the use of paracetamol and ketorolac, the patient still has pain and VAS greater than 3, 25 mg pitadine is given intravenously to the patient and the time of the first application of pethidine, the total amount of pitadine received is recorded. And in the event of any problems and complications (nausea, vomiting, hypotension, etc.), we will treat the patient immediately.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Bu Ali hospital
Full name of responsible person
Dr. Maryam Razavi
Street address
Amir Al Momenin street
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3348 2796
Email
boali@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mohammadhadi Abbasi
Street address
Dr.Hesabi Square , campus of medical sciences
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5744
Email
public@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
Dr Maryam Razavi
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Dr. Hesabi square campus of medical sciences
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
98167-43175
Phone
+98 543329571522
Email
Dr.razavi351@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Maryam Razavi
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Dr.Hesabi square campus of medical sciences
City
Zahedan
Province
Sistan-va-Balouchestan

Postal code
98167-43175
Phone
+98 54 3329 5620
Email
Dr.razavi351@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Maryam Razavi
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Dr.Hesabi Square , campus of medical sciences
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
98167-43175
Phone
+98 54 3329 5620
Email
Dr.razavi351@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available