Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of intravenous paracetamol and ketorolac for prevention of intra-operative shoulder pain in patients undergoing cesarean section under spinal anesthesia

Protocol summary

Study aim
Comparison of the pre-emptive analgesic effect of intravenous paracetamol and ketorolac for prevention of intra-operative shoulder pain in patients undergoing cesarean section under spinal anesthesia
Design
Double Blinded Randomized Clinical Trial
Settings and conduct
In this study , 300 patient in 3 groups in a double-blind placebo-controlled clinical trial will undergo cesarean section at Hafez hospital ,Shiraz.
Participants/Inclusion and exclusion criteria
Inclusion criteria: primi-gravid or second gravid; elective cesarean section (ASA I-II) who have singleton term pregnancy (37 weeks of gestational age or more). Non-inclusion criteria:, hepatic disorders, renal insufficiency, chronic alcoholism, chronic pains, history of peptic ulcer disease, history of abdominal surgery any contraindication to spinal anesthesia.
Intervention groups
Intervention group 1: patients in the ketorolac group will receive 30 mg of ketorolac in 100 cc normal saline during 20 minutes. Intervention group 2: patients in the paracetamol group will receive preventive paracetamol, 1000 mg in 100 cc normal saline during 20 minutes. Control group: Patients in the control group will receive 100 cc normal saline as placebo during 20 minutes.
Main outcome variables
Shoulder Pain; Blood pressure; Heart rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180922041084N4**
Registration date: **2019-10-21, 1398/07/29**
Registration timing: **prospective**

Last update: **2019-10-21, 1398/07/29**
Update count: **0**
Registration date
2019-10-21, 1398/07/29

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-22, 1398/07/30
Expected recruitment end date
2020-01-20, 1398/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of intravenous paracetamol and ketorolac for prevention of intra-operative shoulder pain in patients undergoing cesarean section under spinal anesthesia

Public title
The effect of intravenous paracetamol and ketorolac for

prevention of intraoperative shoulder pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

primi-gravid or second gravid elective cesarean section (ASA I-II) who have singleton pregnancy at term (37 weeks of gestational age or more singleton pregnancy 37 weeks of gestational age or more

Exclusion criteria:

allergy to ketorolac and other NSAIDs allergy to paracetamol asthma gestational diabetes cardiovascular disorders hepatic disorders renal insufficiency chronic alcoholism per-eclampsia bleeding tendency chronic pain history of upper extremity trauma history of peptic ulcer disease history of abdominal surgery any contraindication to spinal anesthesia spinal column fracture

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomized according to the charts which is derived from www.randomization.com site.

Blinding (investigator's opinion)

Double blinded

Blinding description

Neither the participants nor the investigators involved in data collection and assessing the outcomes are aware of the identity of the target drugs used in the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, 7th floor, Shiraz University of Medical Sciences, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.SUMS.MED.REC.1397.358

Health conditions studied

1

Description of health condition studied

cesarean delivery

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

shoulder pain

Timepoint

Before the surgery as baseline measurement and intra-operatively

Method of measurement

numerical rating scale (NRS)

2

Description

Blood pressure

Timepoint

Every five minutes till 20 minutes after spinal anesthesia and the every 10 minutes to the end of the surgery.

Method of measurement

Monitoring

3

Description

Heart rate

Timepoint

Every five minutes till 20 minutes after spinal anesthesia and the every 10 minutes to the end of the surgery.

Method of measurement

Monitoring

Secondary outcomes

1

Description
Hematocrit
Timepoint
Before and after surgery
Method of measurement
Blood sample

Intervention groups

1

Description
Intervention group 1: patients in the ketorolac group will receive 30 mg of ketorolac in 100 cc normal saline during 20 minutes.
Category
Treatment - Drugs

2

Description
Intervention group 2: patients in the paracetamol group will receive preemptive paracetamol 1000 mg in 100 cc normal saline during 20 minutes.
Category
Treatment - Drugs

3

Description
Control group: Patients in the control group will receive 100 cc normal saline as placebo during 20 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Shiraz 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
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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