

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Analgesic effect of paracetamol in pain management after cesarean section

Protocol summary

Study aim

Evaluation of analgesic effect of intravenous paracetamol on pain after cesarean section

Design

240 pregnant women who were candidates for elective cesarean section will be divided into two equal groups (120 subjects) of intervention (pre-operative intravenous paracetamol) and control (no preoperative analgesia) by using the coin throw method. Surgery will be done by someone outside the research team. The investigator and patient are unaware of the grouping (double-blind).

Settings and conduct

Surgery will be performed at the Rafsanjan NIKNAFS Maternity Hospital by a surgeon outside the research group. The operating room nurse determines the group of each patient with a simple randomization method, and each patient's group records in their own record sheet, surgeon, researcher and patient will not aware about the group. The patient's vital signs before, during and after surgery, and pain score immediately after surgery and up to 24 hours afterwards, will be recorded by nurses outside the study group at different intervals.

Participants/Inclusion and exclusion criteria

Inclusive criteria: Pregnant women aged 18 to 35 years old, candidate for elective cesarean section. Exclusive criteria: history of cardiovascular diseases, hypertension, Diabetes, hepatic failure, renal failure, drug abuse, taking psychiatric medications, pain before cesarean section.

Intervention groups

Intervention group: 15 minutes before cesarean section, one gram of intravenous paracetamol will inject into the intervention group. Control group: No analgesic will be given before surgery.

Main outcome variables

The patient's pain score is measured on the basis of VAS at certain intervals after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022320N17**

Registration date: **2019-01-18, 1397/10/28**

Registration timing: **retrospective**

Last update: **2019-01-18, 1397/10/28**

Update count: **0**

Registration date

2019-01-18, 1397/10/28

Registrant information

Name

Tayebeh Mirzaei

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

t.mirzaei@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic effect of paracetamol in pain management after cesarean section

Public title

Analgesic effect of paracetamol in pain management after cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

term pregnancy elective cesarean section

Exclusion criteria:

History of cardiovascular disease Hypertension Diabetes
Hepatic failure Renal failure Drug abuse Taking
psychiatric medications Pain before cesarean

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomized pairing method. Patients with general entry conditions are divided into two groups by throwing coins. When a group reaches 120, the other referrals are assigned to the another group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Neither patients nor the person filling the questionnaire were informed of the prescriptive drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Emam Ali Bolv

City

Rafsanjan

Province

Kerman

Postal code

7718174715

Approval date

2016-11-08, 1395/08/18

Ethics committee reference number

IR.RUMS.REC.1395.115

Health conditions studied

1

Description of health condition studied

After cesarean pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score in visual analog scale

Timepoint

measurement of pain by VAS in 0, 1,2,4,6,12 and 24 hour after cesarean section

Method of measurement

pain measured by VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group of pregnant women who will receive one gram of intravenous Paracetamol half an hour before the onset of cesarean section.

Category

Treatment - Drugs

2

Description

Control group: A group of pregnant women who will not receive any Pain relief medication before cesarean section.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Niknafs Maternity hospital
Full name of responsible person
Fatemh Kordestani
Street address
Shohada Ave.
City
Rafsanjan
Province
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Postal code
7717933777
Phone
+98 34 3425 9030
Email
niknafs@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Shamsizadeh
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vcrt@rums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person

Sakineh Mirzaei Khalilabadi
Position
Assistant Professor
Latest degree
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data file will be ready after the removal of the names of the participants of both groups, so that, upon request and confirmation of the request, they will be available to the individuals or organizations concerned.

When the data will become available and for how long

The data will be available from the publication of the study results up to 10 years later.

To whom data/document is available

Only scholars working in a university or science center will have access to data through the formal application of the Institute.

Under which criteria data/document could be used

Any scientific use of data is permitted.

From where data/document is obtainable

Applicants can obtain data from the researcher.

What processes are involved for a request to access data/document

The applicant will send his official request, which has been confirmed by his scientific or academic center. After verifying the request by the researcher, the data is sent to the applicant.

Comments