Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Analgesic effect of paracetamol in pain managment 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)

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+98 34 3425 5900

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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 managment after cesarean section

Public title
Analgesic effect of paracetamol in pain managment 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
Kerman
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
Street address
Central Organization. Imam Ali Blvd.
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7717933777
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+98 34 3428 0086
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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
Specialist
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Gynecology and Obstetrics
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Person responsible for updating data

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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