

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Efficacy of prophylactic paracetamol injection for pain reduction after cesarean

Protocol summary

Study aim

Efficacy of prophylactic paracetamol injection for pain reduction after cesarean

Design

Two arm parallel group randomised trial with blinded postoperative care and assesment of pain in them after injection paracetamol or placebo 60 cases

Settings and conduct

We entered 60pregnant women in this study in taleghani hospital .we injected 1gr paracetamol or placebo(normal salin) 30 min before begin of cesaren,we ask severity of pain based on VAS score in 1th,6th,18th and 24 thvhour after cesarean .patients in two groups and questioner have no information of get paracetamol or placeo in each cases.

Participants/Inclusion and exclusion criteria

We entered patients with elective cesarean,single tone pregnancy and gestational age more than38week in this study.we exclude patients wih addiction to drug,cardiac,hepatic and pulmonary disease and allergy to paracetamol from this study

Intervention groups

Pregnant women

Main outcome variables

Severity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181001041196N1**

Registration date: **2019-03-25, 1398/01/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-25, 1398/01/05**

Update count: **0**

Registration date

2019-03-25, 1398/01/05

Registrant information

Name

Sahar Yahyapourmalekmian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4265 3306

Email address

sahar_yahyapour@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of prophylactic paracetamol injection for pain reduction after cesarean

Public title

Efficacy of paracetamol for pain reduction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Elective cesarean Spinal anesthesia Single tone pregnancy More than 38weeks pregnancy

Exclusion criteria:

Addiction to drug Cardiac ,hepatic,pulmonary diseases

Allergy to paracetamol

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomized

Blinding (investigator's opinion)
Double blinded

Blinding description
patients are not aware of their allocation as well as outcome assessors.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Arabai street, velenjak

City
Tehran

Province
Tehran

Postal code
4483131872

Approval date
2018-05-01, 1397/02/11

Ethics committee reference number
IR.SBMU.MSP.REC.1397.698

Health conditions studied

1

Description of health condition studied
Pain localized to other parts of lower abdomen

ICD-10 code
R10.3

ICD-10 code description

Pain localized to other parts of lower abdomen

Primary outcomes

1

Description
Pain

Timepoint
1 hour after ceassarean,12hour after cesarean ,18hour after cesarean and 24hour after cesarean

Method of measurement
Vas score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: this group includes thirty 38 weeks pregnant women. 1 gr (100 cc) intravenous prophylactic paracetamol (manufactured by Abidi) at one time, 30 minutes before spinal anesthesia, will be administrated in order to reduce the pain after cesarean section.

Category
Prevention

2

Description
Control group: this group includes thirty 38 weeks pregnant women. 100 cc of intravenous prophylactic normal saline as a placebo at one-time, 30 minutes before spinal anesthesia, will be administrated in order to reduce the pain after cesarean section.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani hospital

Full name of responsible person
Sahar yahyapour

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Arabi street, velenjak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Ali Ziaee
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research deputy of shahid beheshti university of medical sciene
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sahar yahyapour
Position
Resident of obstetrics and gynecology
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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

individual data after removing the identifying variables including name of the patients and file number will be provided for the journal based on the journal policy.

When the data will become available and for how long

6 months after publication the results in the journal.

To whom data/document is available

researchers

Under which criteria data/document could be used

secondary analysis on the primary outcome of the study (pain reduction)

From where data/document is obtainable

Sahar yahyapour

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

Send an email to Sahar Yahyapour and provide information about the reason for the request and the requested variables. After reviewing the full request of the requesting person or institution, the required data will be sent.

Comments