Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Preventive Analgesia with Paracetamol in Post-Cesarean Section Pain Control

Protocol summary

Summary

Pain management is an important component in the care of the post-cesarean patient. Although there have been innovative advances in pain management and new analgesic modalities, a need still exists for safer and more effective analgesics for the management of pain in the post-cesarean setting.The purpose of this clinical trial is to evaluate the efficacy of preventive administration of iv acetaminophen with respect to postoperative pain control and analgesic requirements in patients undergoing cesarean section with spinal anesthesia. In this double blind and placebo-controlled clinical trial 100 term parturients over 18 years age scheduled for cesarean delivery will be randomize to infuse acetaminophen 1 g into 100 ml normal saline (study group, n=50) or normal saline (placebo group, n=50) 20 minuets before the end of operation. Postoperatively, all patients receive paracetamol iv or diclofenac suppository for 24 hr. Visual analogue scale (VAS; 0 to 10), analgesic requirements, and side effects will be record every hour for four hours then every four hours for a total of 24 hr postoperatively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211187013N2**
Registration date: **2012-12-04, 1391/09/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-12-04, 1391/09/14

Registrant information

Name

Simin Atashkhoei

Name of organization / entity

Tabriz University of Medical Siences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Women's Reproductive Research, Tabriz University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Preventive Analgesia with Paracetamol in Post-Cesarean Section Pain Control

Public title

Preventive Analgesia with Paracetamol for Post-Cesarean Section Pain Control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Term parturients; Parturients with over 18 years; Parturients undergoing elective cesarean section with spinal anesthesia. Exclusion criteria: To have a contraindication for spinal anesthesia; To have allergy to local anesthetics; Patients with mental disorders;

Patients with organic dysfunctions; Previous chronic pain; Rased hepatic enzyms.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Vice chancellor for research, Tabriz University of Medical Sciences

Street address
Vice chancellor for research, Tabriz University of Medical Sceinces, Daneshgah Square

City
Tabriz

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
916

Health conditions studied

1

Description of health condition studied
postoperatve pain after cesarean section

ICD-10 code
o75.4

ICD-10 code description
Other complications of obstetric surgery and procedures

Primary outcomes

1

Description
pain

Timepoint
PACU, every 1 hour until 4 hours and then every 4 hours until 24 hours after operation.

Method of measurement
Visual analogue scale (VAS) from 0 (without pain) to 10 (severe and intolerable pain)

Secondary outcomes

1

Description
Analgesic requirements

Timepoint
PACU, every 1 h until 4 h and then every 4 h until 24 h after operation

Method of measurement
Injection number and injection dose in mg

Intervention groups

1

Description
In the study group paracetamol 1 g(volume =6.7ml) into 100 ml normal saline during 15 min, 20 min before the end of operation is infused.

Category
Treatment - Drugs

2

Description
In the placebo group 100 ml normal saline alone during 15 min, 20 min before the end of operation is infused.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Operation Room and Cesarean setting, Al Zahra Hospital,Tabriz University of Medical Sciences

Full name of responsible person
Dr. Simin Atashkhoei

Street address
Al Zahra hospital, Artesh Jonoubi Ave, Operating room, Dr. Simin Atashkhoyi

City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Women's Reproductive Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Elahe Olade Saheb Madarek
Street address
Tabriz, Artesh Jonoubi Ave, Al Zahra hospital
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Women's Reproductive Research Center, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty