

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 randomized to infuse acetaminophen 1 g into 100 ml normal saline (study group, n=50) or normal saline (placebo group, n=50) 20 minutes 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 recorded 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 Sciences

Country

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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 enzymes.

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

postoperative 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Associate Professor, Specialist in Anesthesiology

Other areas of specialty/work

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Web page address

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