

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Preventive Analgesia of Two Different Doses Intravenous Paracetamol in Control of Pain after Gynecologic Laparoscopic Surgery

Protocol summary

Summary

Pain management is a crucial component in the care of the postoperative patient undergoing laparoscopy. Intravenous acetaminophen has been used for the treatment of acute pain. The aim of this clinical trial is to evaluate the analgesic efficacy and safety of preventive doses 2 g compared with 1 g of intravenous acetaminophen in control of postoperative pain in patients undergoing gynecologic laparoscopic surgery. This double-blind, randomized study is conducted in 92 healthy women aged 20-70 years who are randomized to 2 groups; IV acetaminophen 2g (study group; n=46) or IV acetaminophen 1g(control group; n=46) in 100 mL normal saline each given as a 15-minute infusion 20 minute before the end of surgery. Postoperative pain is treated with intravenous meperidine or suppository diclofenac. Pain scores, analgesic consumption and any adverse effects are recorded in PACU and at 1, 2, 3, 6, 12, and 24 h after the operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312147013N5**

Registration date: **2014-02-20, 1392/12/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-20, 1392/12/01

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

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Preventive Analgesia of Two Different Doses Intravenous Paracetamol in Control of Pain after Gynecologic Laparoscopic Surgery

Public title

Effect of prophylactic 2 g paracetamol in reducing of postoperative pain after gynecologic laparoscopy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA class I, II; scheduled for gynecologic laparoscopy; age 20-70 years. Exclusion criteria: laparotomy with laparoscopy; allergy to paracetamol; history of organ system dysfunction(cardiovascular, respiratory, liver, renal, ...); history of psychopathy; history of chronic pain syndrome; pregnancy.

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice Chancellor for Research, Tabriz university of
Medical sciences

Street address

Vice chancellor for research, Tabriz University,
Daneshgah Street, Tabriz

City

Tabriz

Postal code**Approval date**

2014-02-15, 1392/11/26

Ethics committee reference number

92187

Health conditions studied**1****Description of health condition studied**

Acute postoperative pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes**1****Description**

Pain

Timepoint

PACU and at 1, 2, 3, 6, 12, and 24h postoperatively

Method of measurement

visual analogue scale (0= non to 10= severe pain) cm

Secondary outcomes**1****Description**

Postoperative analgesic consumption

Timepoint

PACU and during 24h postoperatively

Method of measurement

number and amount of medication by mg

Intervention groups**1****Description**

In study group: paracetamol 2g into 100 ml normal saline
whiten 15 min, 20 min before the end of operation is
infused.

Category

Treatment - Drugs

2**Description**

In control group: 1g paracetamol into 100 ml normal
saline whiten 15 min, 20 min before the end of operation
is infused.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra Hospital

Full name of responsible person

Dr. Simin Atashkhoyi

Street address

Sought Artesh Street, Al-Zahra Hospital, Tabriz

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tabriz University of
Medical Sciences

Full name of responsible person

Dr. Rashidi

Street address

Vice chancellor for research, Daneshgah Street,
Tabriz

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Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, 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

Anesthesiologist/ Professor

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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