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) in100 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

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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: laparatomy 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
City
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
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Position
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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