

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effect of Intraperitoneal Infiltration of Bupivacaine and Fentanyl Combination on the Pain Control after Diagnostic Gynecologic Laparoscopy

Protocol summary

Summary

Patients undergoing laparoscopic procedures may experience moderate or even severe postoperative pain, frequently in the abdomen or shoulder region. The origin of this pain may be peritoneal or diaphragm. The intraperitoneal (IP) administration of local anesthetics is controversial but has proven effective in some studies for the relief of postoperative pain. Intraperitoneal injection of opioids for postoperative analgesia has been evaluated as an alternative approach. The aim of this study is to investigate analgesic efficacy intraperitoneal injections of local anesthetic and opioid combination on pain control after diagnostic gynecologic laparoscopy. In this randomized, double blind, and placebo-controlled trial, 100 healthy women undergoing gynecologic laparoscopy for diagnosis of infertility under general anesthesia will be studied. At the end of laparoscopy patients will be randomized to infiltrate 40mL of 0.25% bupivacaine with 100 µg fentanyl (study group, n=50) or normal saline (placebo group, n=50) intraperitoneally. 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: **IRCT201212267013N4**

Registration date: **2013-01-06, 1391/10/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-01-06, 1391/10/17

Registrant information

Name

Simin Atashkhoei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3333 3806

Email address

atashkhoei@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Intraperitoneal Infiltration of Bupivacaine and Fentanyl Combination on the Pain Control after Diagnostic Gynecologic Laparoscopy

Public title

Effect of Intraperitoneal Infiltration of Bupivacaine and Fentanyl Combination on the Pain Control after Diagnostic Gynecologic Laparoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients scheduled for diagnostic gynecologic laparoscopy; patients aged 18-40 yr; patients with ASA class I or II. Exclusion criteria: Patients with a history of allergy to local anesthetics; patients with a history of systemic disease or psychological disorders; patients with a history of chronic pain syndrome; Patients with a history of NSAIDS or any other analgesic consumption.

Age

From **20 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 Sciences, Daneshgah square, Tabriz

City

Tabriz

Postal code

Approval date

2012-11-17, 1391/08/27

Ethics committee reference number

91135

Health conditions studied

1

Description of health condition studied

pain due to diagnostic laparoscopy

ICD-10 code

N97

ICD-10 code description

Female infertility

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

Dose of 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(n=50) 40mL of 0. 25% bupivacaine
with 100 µg fentanyl is infiltrated intraperitoneally at the
end of operation.

Category

Treatment - Drugs

2

Description

In the placebo group(n=50) 40 ml normal saline is
infiltrated intraperitoneally at the end of operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra Hospital, Operation Room and postoperative
setting

Full name of responsible person

Dr. Simin Atashkoei

Street address

Al Zahra hospital, Artesh Jonoubi Ave, Operating
room, Dr. Simin Atashkoyi

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. Seyyed Kazem Shakouri

Street address

Tabriz University, Daneshgah Ave, 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

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Associate Professor, Specialist in Anesthesiology

Other areas of specialty/work

Street address

Al Zahra hospital, Artesh Jonoubi Ave, Tabriz

City

Tabriz

Postal code

Phone

+98 41 1553 9161

Fax

Email

siminatashkhoyi@yahoo.comsatashkhoyi@gmail.com

Web page address

Person responsible for scientific 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

Street address

Al Zahra Hospital, Artesh Jonoubi Ave, Tabriz

City

Tabriz

Postal code

Phone

+98 41 1553 9161

Fax

Email

siminatashkhoyi@yahoo.comsatashkhoyi@gmail.com

Web page address

Person responsible for updating data

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

Street address

Alzahra Hospital, Artesh Jonoubi Ave, Tabriz

City

Tabriz

Postal code

Phone

00

Fax

Email

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