

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of efficacy of Bupivacain and Fentanyl in Pre-emptive and Pre-ventive Epidural Analgesia in the patients undergoing Major Gynecologic Surgeries.

Protocol summary

Summary

Our aim in this study is to compare efficacy of epidural administration of analgesics before the initiation of the surgery with administration before the end of surgery in patients undergoing major gynecologic surgeries. Key inclusion criteria is to be over 18 years with an indication for major gynecologic surgery. Main exclusion criteria are having a contraindication for epidural analgesia and to have allergy to analgesics. 50 females over 18 years candidate for major gynecologic surgery in Tabriz Al-Zahra hospital will be divided into two groups of 25. For the patients in group 1, as the group pre-emptive, 20 minutes before the initiation of the surgery, 25 micrograms of fentanyl and 10-12 ml of bupivacain 0.125 as a bolus dose prior to continuous infusion of bupivacain 0.125 with rate of 2ml per minute, would be administered. For the patients in group 2, as group pre-ventive, a bolus dose of 10-12 ml of Bupivacain 0.125 and fentanyl 25 micrograms would be administered 20 minutes before the end of surgery via epidural catheter. All the patients would be admitted to intensive care unit when fully awakened. Administered analgesics dose together with pain scores via visual analogue scale from 0 (without pain) to 10 (with an intolerable pain), as primary outcome measures, would be measured immediately after consciousness (hour 0) and 3, 6, 12 and 24 hours later for the two groups to be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107127013N1**
Registration date: **2011-12-31, 1390/10/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-31, 1390/10/10

Registrant information

Name

Simin Atashkhoei

Name of organization / entity

Tabriz University of Medical Sciences

Country

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+98 41 3333 3806

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atashkhoei@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-06-20, 1390/03/30

Expected recruitment end date

2012-06-19, 1391/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of Bupivacain and Fentanyl in Pre-emptive and Pre-ventive Epidural Analgesia in the patients undergoing Major Gynecologic Surgeries.

Public title

Bupivacain and Fentanyl, before the start of surgery or before the end of surgery?

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: (being over 18 years; having indication for major gynecologic surgery) Exclusion criteria: (to have a contraindication for epidural analgesia; to have allergy to local anesthetics; to have mental disorders; organic dysfunctions; previous chronic pain)

Age

From **18 years** old to **149 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Ethics committee of Tabriz Medical University

Street address

Vice chancellor for research, Tabriz university of medical sciences, Daneshgah square

City

Tabriz

Postal code

Approval date

2011-06-12, 1390/03/22

Ethics committee reference number

9056

Health conditions studied

1

Description of health condition studied

local analgesia in major gynecologic surgeries

ICD-10 code

N94.9

ICD-10 code description

Unspecified condition associated with female genital organs and menstrual cycle

Primary outcomes

1

Description

pain severity

Timepoint

0, 3, 6, 12 and 24 hours after becoming conscious

Method of measurement

using visual pain scoring (VAS) from 0 (without pain) to 10 (severe intolerable pain)

2

Description

Analgesics administered dose

Timepoint

0-3-6-12-24 hours after becoming conscious

Method of measurement

Injection count and injection dose in milli or micro grams

Secondary outcomes

empty

Intervention groups

1

Description

10 to 12 mls of Bupivacain 0.125 together with 25 micrograms of Fentanyl will be injected via epidural catheter as a bolus dose, 20 minutes before the end of the surgery for individuals in the group pre-ventive.

Category

Prevention

2

Description

10 to 12 mls of bupivacain 0.125 and 25 micrograms of fentanyl as a bolus dose, 20 minutes before the initiation of the surgery and bupivacain 0.125 with a rate of 2 ml per minute as a continuous infusion will be administered intra venously for individuals in the group pre-emptive.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra Women's Hospital

Full name of responsible person

Simin Atashkhoyi

Street address

Al Zahra hospital, Baghshomal square

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz Medical University

Full name of responsible person

AliReza Ostadrahimi

Street address

Vice chancellor for research, Tabriz University of
medical sciences, Daneshgah square

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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

Tabriz Medical University

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 Medical University

Full name of responsible person

Simin Atashkhoyi

Position

Associate Professor, Specialist in Anesthesiology

Other areas of specialty/work

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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