Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 adminstration 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

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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) Exclution 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 sceinces, 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 administerd 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
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Vice chancellor for research, Tabriz University of medical sceinces, 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
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Simin Atashkhoyi
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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