Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of Postoperative Pain after Gynecologic Oncologic Surgery Epidural and Intravenous

Protocol summary

Summary

Patients with major surgeries for gynecologic cancers need an appropriate protocol for control of acute postoperative pain. The aim of this study is to compare two techniques of intravenous patient control analgesia(PCA) and epidural PCA (PCEA) with a combined therapy in order to reach to an effective pain control with lower complications, earlier patient mobilization and lower admission time. 90 women with gynecologic malignancy who are candidate for surgery will be divided randomly in two groups . all patients will undergo to general anesthesia, group PCEA will receive epidural catheter from L3-L4 interspaces and only test dose will be administrated. After surgery, for group PCA analgesia medication will be infused, which contain 300 µg (6ml) fentanyl, 200mg((4ml) petidine and 8mg(2ml) ondansetron in Normal saline with the total volume of 100 ml. group 2 will receive Bupivacaine 0.5% 100 mg (24ml), fentanyl 150 µg (3ml) in Normal saline with total volume of 100 ml. rate of infusion in two groups will be 6-8 ml/h and blouse administration of 2 ml every 15 minute as needed. Severity of pain will control and record, at 2, 4. 6, 8, 12, 24, 36 and 48 hours postoperatively and during first patient mobilization. Additional analgesia with 0.1 mg / kg morphine will administrated if needed and will record. Any complication such as nausea, vomiting, respiratory depression, itching, sedation and in epidural group lower extremities parasthesia and any other complications evaluate and will record.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071411700N2**
Registration date: **2013-08-29, 1392/06/07**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-08-29, 1392/06/07

Registrant information

Name

Farnaz Moslemi Tabrizi

Name of organization / entity

Alzahra hospital, Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1553 9161

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Recruitment status

Recruitment complete

Funding source

Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Postoperative Pain after Gynecologic Oncologic Surgery Epidural and Intravenous

Public title

Comparison of Patient-Controlled Epidural Analgesia with Intravenous Patient-Controlled Analgesia on Postoperative Pain Control after Major Gynecologic

Oncologic Surgery-A Randomized controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women’s with gynecologic Oncologic Surgery in the operation list of Alzahra Hospital; Women’s with ASA class I and II; patients who wannt to contribute in the study Exclusion criteria: Women’s with ASA class III or higher; Severe cardiovascular diseases; Epidural anesthesia contraindications;Coagulation disorders or antiquagulant drugs using with therapeutic dose; Spin anomalies; Sepsis; Hypovolemic shock

Age

No age limit

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of medical Sciences

Street address

Daneshgah Ave, Tabriz University of medical Sciences

City

Tabriz

Postal code

Approval date

2013-03-11, 1391/12/21

Ethics committee reference number

91224

Health conditions studied

1

Description of health condition studied

Postoperative Pain Control after Gynecologic Oncologic Surgery

ICD-10 code

C51-58

ICD-10 code description

Malignant neoplasms of female genital organs

Primary outcomes

1

Description

Postoperative analgesia

Timepoint

Postoperative 2, 4, 6, 8, 12, 24 and 36 hours

Method of measurement

Severity os pain with Visual Analoge Scale(VAS)

Secondary outcomes

1

Description

Sedation

Timepoint

Posoperative 4, 6, 8, 12, 24, 36 hours

Method of measurement

Modified Ramsy sedation scale

2

Description

Patient's satisfaction

Timepoint

On the fifth day postoperative

Method of measurement

Score according to postoperative analgesia (nil = 0;

3

Description

Nausea and vomiting

Timepoint

Postoperative 2, 4, 6, 8, 12, 24, 36 hours

Method of measurement

Severity of Nausea and vomiting with Belville scorhng

Intervention groups

1

Description

After surgery, In recovery room for group one (IPCA) or which group that will receive intra venous PCA, analgesic will be infused, which contain 300 µg (6ml) fentanyl, 200mg (4ml) petidine and 8mg(2ml) ondansetron in Normal saline 0.9% with the total volume of 100 ml. First the speed of infusion will be ml/h 8-6, blouse administration of 2 ml every 15 minute are given by patient as needed.

Category

Treatment - Drugs

2

Description
Group 2 PCEA will receive epidural catheter from L3-L4 interspaces and only test dose(lidocaine 1.5% 3-4 ml and Epinephrine 1/200000) will be administrated. Group 2 will receive Bupivacaine 0.5% 100 mg fentanyl 150 µg (3ml)in Normal saline with total volume of 100 ml. Rate of infusion will be 6-8 ml/h and blouse administration of 2 ml every 15 minute as needed.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
Dr. Farnaz Moslemi

Street address
Alzahra Hospital, South artesh Ave

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person
Ellahi Saheb Madarek

Street address
Al Zahra hospital, South Artesh ave

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Women's Reproductive Health Research Center, 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
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person
Dr. Farnaz Moslemi

Position
Associate Professor, anesthesiologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position
Associated Professor, Specialist in Anesthesiology

Other areas of specialty/work

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Person responsible for updating data

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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