

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of epidural saline washout versus receiving nothing on regression of sensory and motor block after epidural anesthesia with Marcaine 0.5% and fentanyl in gynecologic surgery: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of epidural saline washout versus receiving nothing on regression of sensory and motor block after epidural anesthesia with Marcaine 0.5% and fentanyl in gynecologic surgery

Design: a double blinded randomized clinical trial.

Setting and conduct: All eligible patients who are candidate for cystocele or rectocele and will refer to the Fatemeh Hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a); candidate for cystocele or rectocele; (b) Having ASA class I or II.

Exclusion criteria: (a) having intracranial pressure; (b) having hemodynamic disorder. **Intervention:** infusion of 30 ml normal saline single dose through epidural catheter after surgery. **Control:** receive nothing. **Primary outcome:** (a) assessing regression of sensory block every 10 min immediately after operation using cotton soaked in alcohol and pin prick until regression to 2 or 3 segments; (b) assessing regression of motor block every 10 min immediately after operation using Bromage scoring scale until regression to 1 or 2 score. **Secondary outcome:** (a) assessing post operational pain immediately after surgery and 30 min, 1, 2, 6, and 12 hours later using VAS scoring scale; (b) mean arterial pressure immediately after surgery and 30 min, 1, 2, 6, and 12 hours later using manometer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404279014N34**
Registration date: **2014-05-03, 1393/02/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-03, 1393/02/13

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of epidural saline washout versus receiving nothing on regression of sensory and motor block after epidural anesthesia with Marcaine 0.5% and fentanyl in

gynecologic surgery: a double blinded randomized clinical trial

Public title

Effect of epidural saline washout versus receiving nothing on regression of sensory and motor block after epidural anesthesia with Marcaine 0.5% and fentanyl in gynecologic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a); candidate for cystocele or rectocele; (b) Having ASA class I or II. Exclusion criteria: (a) having intracranial pressure; (b) having hemodynamic disorder.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The first patient will be randomly assigned to intervention and control group using random number table. Then, other patients in order will be randomly assigned to either of the two groups. Blinding: The patients will be unaware of the intervention during surgery. In addition, the physician, who conduct the intervention is different from the physician who will examine the patients and the examiner will not be aware of the intervention. Therefore, the trial will be run as double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid

Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2014-03-10, 1392/12/19

Ethics committee reference number

D/P/16/35/9/110

Health conditions studied

1

Description of health condition studied

Cystocele

ICD-10 code

N81.1

ICD-10 code description

Cystocele

2

Description of health condition studied

Rectocele

ICD-10 code

N81.6

ICD-10 code description

Rectocele

Primary outcomes

1

Description

assessing regression of sensory block

Timepoint

every 10 min immediately after operation until regression to 2 or 3 segments

Method of measurement

using cotton soaked in alcohol and pin prick

2

Description

assessing regression of motor block

Timepoint

every 10 min immediately after operation until regression to 1 or 2 score

Method of measurement

using Bromage scoring scale

Secondary outcomes

1

Description

assessing post operational pain

Timepoint

immediately after surgery and 30 min, 1, 2, 6, and 12 hours later

Method of measurement

using VAS scoring scale

2

Description

mean arterial pressure

Timepoint

immediately after surgery and 30 min, 1, 2, 6, and 12 hours later

Method of measurement

using manometer

Intervention groups

1

Description

infusion of 30 ml normal saline single dose through epidural catheter after surgery

Category

Treatment - Drugs

2

Description

receive nothing

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Dr Yaser Amirabadi

Street address

Fatemieh Hospital, Pasdaran Ave

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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 the Technology, Hamadan 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

Beasat Hospital

Full name of responsible person

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Position

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Person responsible for updating data

Contact

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