Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the efficacy of standard spinal anesthesia and transversus abdominis plane block with Ropivacaine 0.5% on relieving the postoperative pain after laparoscopic gynecologic surgery

Protocol summary

Study aim

Determination of the effect of transversus abdominis plane block with Ropivacaine 0.5% in relieving postoperative pain after laparoscopic gynecologic surgery

Design

This study is a clinical trial with a control group, parallel-group design, double-blinded and randomized.

Settings and conduct

The population of the study included 200 women candidates for elective laparoscopic gynecologic surgery who referred to Alzahra hospital in Isfahan during 2016-2017. The intervention is done at the operating room. Severity of pain and nausea and vomiting is recorded at the time of recovery, at 30 minutes, 2, 4, 6, 12, and 48 hours after surgery. For evaluating the severity of pain, visual analogue scale (VAS), based on a score of 0 (painless) to 10 (most pain) was used. Peptidine and diclofenac suppository were used if necessary at the time of no pain reduction (pain more than 3). Nausea and vomiting were also determined based on a score of 0 to 3 (0 means non-existence, 1 means mild, 2 means moderate and 3 means severe).

Participants/Inclusion and exclusion criteria

Inclusion criteria : Candidate for laparoscopic gynecologic surgeries (such as ovarian cystectomy and hysterectomy); willingness to participate in the study. Exclusion criteria: Having a history of allergy to the agents used in the study; suffering from acute and/or chronic preoperative pains.

Intervention groups

Intervention group: In this group, in addition to standard spinal anesthesia, an anesthetic drug Ropivacaine (Naropin,0.5%) was injected at a dose of 0.5 mg / kg between transverse abdominal muscle and internal oblique muscle facia. Control group: Patients in this group just received standard spinal anesthesia.

Main outcome variables

severity of pain; severity of nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042618N3**
Registration date: **2019-03-31, 1398/01/11**
Registration timing: **retrospective**

Last update: **2019-03-31, 1398/01/11**
Update count: **0**

Registration date

2019-03-31, 1398/01/11

Registrant information

Name
najme bagheri
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3224 8235
Email address
st_bagherin@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-19, 1395/02/30

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2016-05-19, 1395/02/30

Actual recruitment end date

2018-01-21, 1396/11/01

Trial completion date

2018-05-02, 1397/02/12

Scientific title

Comparing the efficacy of standard spinal anesthesia and transversus abdominis plane block with Ropivacaine 0.5% on relieving the postoperative pain after laparoscopic gynecologic surgery

Public title

The effect of transversus abdominis plane block with Ropivacaine on postoperative pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for laparoscopic gynecologic surgery (such as ovarian cystectomy and hysterectomy) Willingness to participate in the study

Exclusion criteria:

Having a history of allergy to the agents used in the study suffering from acute and/or chronic preoperative pains

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

200 eligible patients were recruited to the study through easy non-randomization method. Then we randomly assigned patients to a treatment or control groups through simple randomization method using random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were randomly assigned to one of the two groups before surgery. Then their group was recorded by the ward secretary and the list was given to the anesthetist. The patients were kept unaware from the groups they were allocated. Then the patients in the intervention group underwent transversus abdominis plane block by an anesthetist. After the surgery, a student who was unaware of the allocation, completed the post-operative pain and other symptoms cheklists and delivered to the secretary.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Esfahan University of Medical Sciences

Street address

Isfahn University of Medical Sciences, Hezar jarib street

City

Esfahan

Province

Isfehan

Postal code

7346181746

Approval date

2017-12-04, 1396/09/13

Ethics committee reference number

IR.MUI.REC.1396.913

Health conditions studied

1

Description of health condition studied

Pain after laparoscopic gynecologic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of pain

Timepoint

At the time of recovery, 30 minutes, 2, 4, 6, 12, and 48 hours after surgery

Method of measurement

VAS (Visual analogue scale)

2

Description

Severity of nausea and vomiting

Timepoint

At the time of recovery, 30 minutes, 2, 4, 6, 12, and 48 hours after surgery

Method of measurement

Based on questionnaire and its scoring (0 = no nausea and vomiting, 1 = mild, 2 = moderate and 3 = severe)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, in addition to standard spinal anesthesia, an anesthetic drug Ropivacaine (Naropin,0.5%) was injected at a dose of 0.5 mg / kg between transverse abdominal muscle and internal oblique muscle facia.
Category
Prevention

2

Description
Control group: Patients in this group just received standard spinal anesthesia.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital in Isfahan
Full name of responsible person
Ata Allah Ghahiri
Street address
Alzahra Hospital, Sofe Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 1668 5555
Email
alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ziba Farajzadegan
Street address
Isfahan University of Medical Sciiences, Hezar jerib Ave
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Postal code
7346181746
Phone
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Email
farajzadegan@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Atoullah Ghahiri
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Obstetric and gynecology department, Alzahra Hospital, Sofe street
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ata Allah Ghahiri
Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

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Email

ghahiri@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available