

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 fascia. 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 checklists 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

Isfahan

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 fascia.

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

Isfahan

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

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Isfahan University of Medical Sciences, Hezar jerib Ave

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7346181746

Phone

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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

City

Isfahan

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8174673461

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ghahiri@med.mui.ac.ir

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
Street address
Obstetric and gynecology department, Alzahra
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Person responsible for updating data

Contact

Name of organization / entity
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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