Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effect of general anesthesia and spinal anesthesia with and without lidocaine on pain level following gynecologic laparoscopic surgeries

Protocol summary

Summary

The aim of this study is detecting the prevention effect of sub- diaphragmatic lidocaine infiltration on reliefing shoulder pain in women laparoscopic surgeries under spinal anesthesia. This is a randomized, single blinded, single center study with control group which will be done in Arash women hospital, laparoscopic ward. Women aged 15- 45 years old who referred to infertility clinic in class of 1&2ASA and need laparoscopic surgery for assessing infertility and ectopioc pregnancy will be included the study. Patients with contraindications of spinal, history of abdominal surgery; history of psychological diseases and anxiety and BMI more than 35 will be excluded. Sample size is 76 patients who will be divided into 3 groups with 28 members randomly. Control group will be generally anesthetized. The first intervention group will be anesthetized in spinal position with spraying of 1 cc of 1% lidocaine solvent into sub-diaphragmatic space and, the second intervention group will be anesthetized just in spinal position without lidocaine. The level of pain will be measured in times of 0, 2, 4, 6 and 12 hours after and during the surgery with VAS (patients will receive paracetamol 6 hours after the surgery routinely and if they have pain, 50 mg pethidine IM will be administered and the dosage will be recorded.If pain score is more than 5 diclofenac suppository will be administered and the dosage will be recorded). Patient satisfaction of anesthesia will be estimated and numbered from 0- 10. The out of bed of patient, vomiting and nausea, headache, using of analgesic and opiod will be compared in 3 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022226698N1**
Registration date: **2016-03-23, 1395/01/04**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2016-03-23, 1395/01/04

Registrant information

Name
Mahroo Rezaeinejad
Name of organization / entity
Tehran University of Medical Science
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2016-04-19, 1395/01/31

Expected recruitment end date

2016-07-21, 1395/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of general anesthesia and spinal anesthesia with and without lidocaine on pain level following gynecologic laparoscopic surgeries

Public title

Effect of 3 methods of general anesthesia and spinal anesthesia with and without lidocaine on pain after women laparoscopic surgeries

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: age between 15-45; women in class of 1&2ASA who need laparoscopic surgery for assessing infertility and ectopioc pregnancy Exclusion criteria: contraindications of spinal, history of abdominal surgery; history of psychological diseases and anxiety; BMI> 35
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **76**
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
Tehran University of Medical Science
Street address
Qods St, Keshavarz Blvd
City
Tehran
Postal code
Approval date
2016-02-15, 1394/11/26
Ethics committee reference number
IR.TUMS.REC.1394.1967

Health conditions studied

1

Description of health condition studied
non inflematory disease of women genital
ICD-10 code
(N80-N98)
ICD-10 code description
Diseases of the genitourinary system (N00-N99)
Noninflammatory disorders of female genital tract

Primary outcomes

1

Description
Pain after surgery
Timepoint
o, 2, 4, 6 and 12 hours after surgery and in discharge
Method of measurement
Visual analog scale

2

Description
satisfaction of anesthesia method
Timepoint
after discharge
Method of measurement
numbered scale from 0- 10

Secondary outcomes

1

Description
Headache
Timepoint
After surgery till discharge
Method of measurement
Questioneer

2

Description
vomiting and nausea amount
Timepoint
After surgery till discharge
Method of measurement
questioneer

3

Description
The amount of opiod and analgesic drug administration
Timepoint
After surgery till discharge
Method of measurement
Check list

Intervention groups

1

Description
Intervention in first control group: Spinal anesthesia is done by 20 mg Bupivacaine 0/5% and then about 15 minutes after spinal anesthesia, the surgery begins. Before any painful stimuli a rectal diclofenac suppository is administered. Then the gas is entered into the abdomen by a needle in lithotomy position and umbilical

trocar is inserted. 10 cc of 1% lidocaine is sprayed into the space below the diaphragm.

Category

Prevention

2

Description

The second intervention group: Spinal anesthesia is done by 20 mg bupivacaine 0/5%.

Category

Prevention

3

Description

Intervention in control group: general anesthesia

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Hospital

Full name of responsible person

Mah-rou Rezaee-Nejad

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences , Deputy of Research

Full name of responsible person

Dr.Younesian

Street address

Qods St, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences , Deputy of Research

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

Arash Women 's Hospital , Tehran University of Medical Sciences

Full name of responsible person

Mahroo Rezaeinejad

Position

women specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arash Women 's Hospital , Tehran University of Medical Sci

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Position

associated professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Mahroo Rezaeinejad

Position

women specialist

Other areas of specialty/work

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Fax

Email

Web page address

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