

# 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 relieving 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 ectopic 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 opioid 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7771 9922

###### Email address

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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 ectopic 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 inflammatory 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

0, 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

Questioner

### 2

#### Description

vomiting and nausea amount

#### Timepoint

After surgery till discharge

#### Method of measurement

questioner

### 3

#### Description

The amount of opioid 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

trocac 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**

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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**

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****Street address**

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Arash Women 's Hospital , Tehran University of Medical Sci

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**Position**

associated professor

**Other areas of specialty/work****Street address**

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**Full name of responsible person**

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**Position**

women specialist

**Other areas of specialty/work**

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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*