

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Clinical trial of comparison between transverse abdominal plane block versus local infiltration of anesthesia in post operative laparoscopic pain among Endometriosis patients

#### Protocol summary

##### Summary

This randomized clinical trial is done between 2015 to 2016 at Avicenna and Mohebe Kosar hospital among 75 women with endometriosis and candidate for laparoscopy who are 18 to 50 years old and ASA classification less than 3 which randomize by balanced block randomization. Patients divide in three groups of: TAP block, local infiltration and placebo. TAP block group receive 0.6 milliliter per kilogram normal saline subcutaneously before incision for trocar as placebo and at the beginning 0.6 milliliter per kilogram Bupivacaine 0.25% inject under laparoscopic guide by using needle number 22G between internal oblique and transverse abdominal muscle after negative aspiration and two POP sensation which divide equally in 4 places at right and left side. Local infiltration group receive 0.6 ml per kg Bupivacaine 0.25% subcutaneously before skin incision for trocar in four places with equal volume and at the beginning receive 0.6 milliliter per kilogram normal saline as placebo in equal volume which divide in 4 places between internal oblique and transverse abdominal plane at right and left side. Placebo group receive 0.6 ml per kg normal saline as placebo for local infiltration and transverse abdominal plane. The person who infiltrates drug is a surgeon and blind to the kind of drug. after that demographic of patients, kind of surgery, duration of surgery and pain score which measured by verbal numerical rating scale (VNRAS) is asked at 2 to 4, 6 to 8, 10 to 12, and 24 hours after surgery and also asked for nausea, vomiting and analgesia consumption which registered in a form.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015090919373N2**

Registration date: **2016-03-24, 1395/01/05**

Registration timing: **na**

Last update:

Update count: **0**

##### Registration date

2016-03-24, 1395/01/05

##### Registrant information

###### Name

Roxana Kargar

###### Name of organization / entity

Avicenna Research Institute

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2221 7065

###### Email address

afsanehnainie@sbmu.ac.ir

##### Recruitment status

**Not enough for processing**

##### Funding source

Avicenna Research Institute

##### Expected recruitment start date

2016-01-15, 1394/10/25

##### Expected recruitment end date

2015-08-21, 1394/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of comparison between transverse abdominal plane block versus local infiltration of

anesthesia in post operative laparoscopic pain among  
Endometriosis patients

## Public title

The effect of Transverse abdominal plane block and local infiltration of anesthesia in post operative laparoscopic pain

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Women between 18 to 50 years old; ASA classification less than 3 ; candidate for elective laparoscopic surgery for endometriosis; take consent for entrance; no addiction to opiate; no companion with other illnesses such as liver, kidney, or psychotic diseases. Exclusion criteria: Tendency of patient for exclusion; allergy to drugs; laparoscopic surgery converted to laparotomy; coagulopathy disease; patients without cooperation; hospitalize less than 24 hours; bowel anastomosis

## Age

From **76 years** old to **44 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **75**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Avicenna

##### Street address

No 97, Yakhchal avenue, Shariati street

##### City

Tehran

##### Postal code

#### Approval date

2015-11-17, 1394/08/26

#### Ethics committee reference number

IR.ACECR.Avicenna.REC.1394.12

## Health conditions studied

### 1

#### Description of health condition studied

Endometriosis of uterus

#### ICD-10 code

N80.0

#### ICD-10 code description

Endometriosis of uterus Adenomyosis

### 2

#### Description of health condition studied

Endometriosis of ovary

#### ICD-10 code

N80.1

#### ICD-10 code description

Endometriosis of ovary

### 3

#### Description of health condition studied

Endometriosis of fallopian tube

#### ICD-10 code

N80.2

#### ICD-10 code description

Endometriosis of fallopian tube

### 4

#### Description of health condition studied

Endometriosis of pritoneum

#### ICD-10 code

N80.3

#### ICD-10 code description

Endometriosis of pelvic peritoneum

### 5

#### Description of health condition studied

Endometriosis of recovagina

#### ICD-10 code

N80.4

#### ICD-10 code description

Endometriosis of rectovaginal septum and vagina

### 6

#### Description of health condition studied

Endometriosis of intestine

#### ICD-10 code

N80.5

#### ICD-10 code description

Endometriosis of intestine

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

Severity of post operative pain in 2 to 4 , 6 to 8 , 10 to 12 and 24 hours after surgery

**Method of measurement**

Ask patients by VNRS scale

## Secondary outcomes

### 1

**Description**

Nausea

**Timepoint**

2 to 4, 6 to 8, 10 to 12, and 24 hours after surgery

**Method of measurement**

Patient expression

### 2

**Description**

Vomiting

**Timepoint**

2 to 4, 6 to 8, 10 to 12, and 24 hours after surgery

**Method of measurement**

Number of vomiting

### 3

**Description**

Morphine consumption

**Timepoint**

2 to 4, 6 to 8, 10 to 12, and 24 hours after surgery

**Method of measurement**

miligramme

### 4

**Description**

Time of first injection of morphine

**Timepoint**

2 to 4, 6 to 8, 10 to 12, and 24 hours after surgery

**Method of measurement**

Hour

### 5

**Description**

Complication of injection

**Timepoint**

2 to 4, 6 to 8, 10 to 12, and 24 hours after surgery

**Method of measurement**

Yes, No

## Intervention groups

### 1

**Description**

Transverse abdominal plane block group receive 0.6 milliliter per kilogram normal saline subcutaneously before incision for Trocar as placebo and at the beginning inject 0.6 milliliter per kilogram Bupivacaine 0.25% by using needle number 22G between internal

oblique and transverse abdominal muscle after negative aspiration and two POP sensation under laparoscopic guide which divided equally in 4 places at right and left side.

**Category**

Treatment - Drugs

### 2

**Description**

Local infiltration group receive 0.6 milliliter per kilogram Bupivacaine 0.25% subcutaneously at the beginning before skin incision for trocar in four places in equal volume and 0.6 milliliter per kilogram normal saline as placebo under laparoscopic guide between internal oblique and transverse abdominal muscle in four places with equal volume in right and left side.

**Category**

Treatment - Drugs

### 3

**Description**

Placebo group receive 0.6 milliliter per kilogram normal saline subcutaneously as placebo in four places in equal volume before skin incision for trocar and then 0.6 milliliter per kilogram normal saline as placebo under laparoscopic guide in four places in equal volume between internal oblique and transverse abdominal plane in right and left side.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Avicenna center and Mohebe Kosar hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Avicenna Research Institute

**Full name of responsible person**

Haleh Maleki

**Street address**

Daneshjoo street, Velenjak

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes  
**Title of funding source**  
Avicenna Research Institute  
**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**  
Avicenna Research Institute  
**Full name of responsible person**  
Roxana Kargar  
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## Person responsible for scientific inquiries

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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*