

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

the Effect of intraperitoneal Bupivacaine in comparison with Dexmedetomidine with Bupivacaine Spray on pain reduction after laparoscopic Endometrial Surgery, A Randomized Clinical Trial

Protocol summary

Study aim

the Effect of intraperitoneal Bupivacaine in comparison with Dexmedetomidine with Bupivacaine Spray on pain reduction after laparoscopic Endometrial Surgery, A Randomized Clinical Trial

Design

This randomized clinical trial will be performed on 45 individuals with Endometrioma who will be referred to Rasoul Akram Hospital. The patients are randomly assigned to three groups of 15 people using a random number table with Excel software, a) the treatment group with bupivacaine b) The treatment with bupivacaine with dexmedetomidine c) The group without medication. This study will be performed as a single blind method.

Settings and conduct

This randomized clinical trial will be performed on 45 individuals with Endometrioma who will be referred to Rasoul Akram Hospital. The patients will be randomly assigned to three groups of 15 people. This study will be performed as a single blind method.

Participants/Inclusion and exclusion criteria

inclusion criteria: having informed consent; laparoscopic surgery due to benign gynecologic diseases; age 20 to 65 years old Exclusion criteria: dissatisfaction, People who use these drugs are harmful to them

Intervention groups

In this study, the intervention was bupivacaine treatment or bupivacaine treatment with doxedmodine and non-medicated group.

Main outcome variables

Pain after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150817023666N11**

Registration date: **2018-04-09, 1397/01/20**

Registration timing: **retrospective**

Last update: **2018-04-09, 1397/01/20**

Update count: **0**

Registration date

2018-04-09, 1397/01/20

Registrant information

Name

Abolfazl Mehdizadeh kashi

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 216651500

Email address

mehdizadeh.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the Effect of intraperitoneal Bupivacaine in comparison with Dexmedetomidine with Bupivacaine Spray on pain reduction after laparoscopic Endometrial Surgery, A Randomized Clinical Trial

Public title

the Effect of intraperitoneal Bupivacaine in pain reduce

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent to enter the study Candidate for laparoscopic surgery due to benign gynecological disease Age between 20 and 65 years Patients ASA I, II women with endometriosis

Exclusion criteria:

Patients who have not signed the consent form Patients whose laparoscopic surgery has changed to vaginal or abdominal Patients that underwent surgery without general anesthesia Pregnant women Allergy to local anesthetics or Dexmedetomidine Patients with morbid obesity Patients with liver or kidney failure

Age

From **20 years** old to **65 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to three groups of 15 people, using the random numbers table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants and outcome evaluators will not be informed of random allocation. For this purpose, before the random allocation, a full explanation of the intervention was given to the patient, Patients will not be informed about random allocation. The outcome evaluators will not be aware of the allocation of patients to study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic commitee of Iran University of Medical science

Street address

Next to Milad Tower, Hemmat hayway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2016-09-14, 1395/06/24

Ethics committee reference number

IR.IUMS.rec.1395.27252

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80.0

ICD-10 code description

Endometriosis of uterus

Primary outcomes

1

Description

Pain

Timepoint

before surgery and 2,4 ,6 ,12 and 24 Hour after surgery

Method of measurement

Visual analog score

Secondary outcomes

empty

Intervention groups

1

Description

First group: intra peritoneal bupivacaein spray (50 cc 0.25%) this intervention will be performed at the end of the procedure.

Category

Treatment - Drugs

2

Description

second group: intraperitoneal bupivacaein(50 cc .25%)with DEX(1 micro g/kg) spray this intervention will be performed at the end of the procedure

Category

Treatment - Drugs

3

Description

control group: intraperitoneal normal saline spray this intervention will be performed at the end of the procedure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-e-Akram Hospital

Full name of responsible person

Abolfazal Mehdizadeh kashi

Street address

Rasool Akram Hospital, Nayesh Avenue, Sattar Khan Avenue, Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2562

Email

amehdizadehkashi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Kazem Malekouti

Street address

Iran University Of Medical science, side of milad tower, Hemmat highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

PR@iums.ac.ir

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Zahra Najmi

Position

Professor of Obstetrics and Gynecology, Fellowship of minimally invasive gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Niayesh Av, Sattar khan st, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449613131

Phone

+98 21 6650 9283

Fax

Email

amehdizadehkashi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abolfazl Mehdizadeh Kashi

Position

Professor of Obstetrics and Gynecology, Fellowship of minimally invasive gynecology

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Street address

Niayesh Av. Sattar khan st. Tehran, Iran.

City

Tehran
Province
Tehran
Postal code
1449613131
Phone
+98 21 6650 9283
Fax
Email
amehdizadehkashi@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Pasture Institute of Iran
Full name of responsible person
Abolfazal Mehdizadeh kashi
Position
Professor of Obstetrics and Gynecology, Fellowship of minimally invasive gynecology
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Specialist
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Gynecology and Obstetrics
Street address
Niayesh Av. Sattar khan st. Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1449613131
Phone
+98 21 6650 9283

Fax
Email
amehdizadehkashi@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Total data without personal information

When the data will become available and for how long

after publication of paper

To whom data/document is available

Researchers

Under which criteria data/document could be used

further research

From where data/document is obtainable

Dr.Rokhgireh s.rokhgireh@gmail.com

What processes are involved for a request to access data/document

Request via E-mail

Comments