

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical Trial Comparing The Effects Of Injection And Non-injection Transcervical Intrauterine Bupivacaine For The Management Of Postoperative Pain Following Uterine Curettage Under General Anesthesia

Protocol summary

Summary

This study is a randomized double-blind clinical trial. The aim of this study is to assess the effect of transcervical intrauterine bupivacaine injection of postoperative pain following uterine curettage under general anesthesia in 70 patients with ages: 18-50 years old. The patients with heart disease and convulsion will be excluded. The patients are randomly divided into two groups. Anesthesia induction in two groups is identical with 2 mg of midazolam and 50 µg of fentanyl and 0.5 mg/kg of Propofol and ventilation with 50% nitrous oxide by face mask. First group receives 15 ml of bupivacaine (0.125 %) using a urinary catheter which is directly proportional to the size of the outlet of the cervix. After 15-20 minutes, the urinary catheter is extracted from the cervix cavity. Second group does not receive bupivacaine. The patients do not know that they have received bupivacaine or not and evaluation of patients is performed by anesthesiologist who does not know about the protocol of the study. The severity of pain in patients will be assessed with a visual analog scale after injection of bupivacaine. The patients will receive 100 mg diclofenac suppository If visual analog scale is more than three.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010616119N3**
Registration date: **2015-01-30, 1393/11/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-30, 1393/11/10

Registrant information

Name

Reza Akhondzadeh

Name of organization / entity

Imam Khomeini Hospital

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial Comparing The Effects Of Injection And Non-injection Transcervical Intrauterine Bupivacaine For The Management Of Postoperative Pain Following Uterine Curettage Under General Anesthesia

Public title

The Effect of Bupivacaine in The Prevention of

Postoperative Pain Curettage

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion Criteria: Woman undergoing curettage surgery.
Exclusion Criteria: History of heart disease; Convulsion;
Sensitivity to local anesthetic.

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The table of random numbers used for randomization, A code will be assigned to each patient by a person who does not know about the protocol of the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jondishapour University Of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jondishapour University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Postal code

Approval date

2015-03-01, 1393/12/10

Ethics committee reference number

Ajums.REC.1393.316

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

Y45

ICD-10 code description

Analgesics, antipyretics and anti-inflammatory drugs

Primary outcomes

1

Description

pain

Timepoint

1, 2, 3, 4, 8 and 12 hours after injection of bupivacaine

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Group I: Transcervical intrauterine injection of 15 ml of bupivacaine (0.125 %) using a urinary catheter after anesthesia.

Category

Prevention

2

Description

Group II: Patients does not receive bupivacaine (Control group) .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Fereshteh Amiri

Street address

Imam Khomeini Hospital, Shahid Ahvazian St., Ahvaz

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Nader Saki

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Vice chancellor For Research Of Ahvaz Jondishapour
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City

Ahvaz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor For Research Of Ahvaz Jondishapour
University of Medical Sciences

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

Imam Khomeini Hospital

Full name of responsible person

Reza Akhondzadeh

Position

Anesthesiologist

Other areas of specialty/work

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Pain Research Center

Full name of responsible person

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Position

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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