Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of diluted ropivacaine in uterine distending fluid on pain after hysteroscopy surgeries

Protocol summary

Study aim
The effect of rupivacaine diluted in dilating fluid on pain after hysteroscopic surgery
Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients, used the random function of Excel software rand for randomization.
Settings and conduct
The study is double-blind. It will be performed at the Endometriosis Research Center of Iran University of Medical Sciences, Hazrat Rasool Akram Hospital. In the intervention group, diluted pivocaine (10 cc of half-percent ropivacaine per 1000 cc of normal saline per liter) will be given as a dilating fluid during hysteroscopy. The control group consisted of 30 patients will receive 10 cc of normal saline per 1000 cc of normal saline per liter as a dilating fluid during hysteroscopy.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Women candidates for hysteroscopy treatment based on the opinion of a specialist; Conscious consent to participate in the study. Exclusion criteria: Presence of pelvic inflammatory disease, malignancy, drug sensitivity, neurological disorders, tube obstruction, pelvic pain
Intervention groups
Dilute ropivacaine (10 cc of half a percent ropivacaine per 1000 cc of normal saline per liter) is given as a dilating fluid during hysteroscopy
Main outcome variables
Intensity and frequency of pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160527028109N4**
Registration date: **2021-05-11, 1400/02/21**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-11, 1400/02/21**
Update count: **0**
Registration date
2021-05-11, 1400/02/21

Registrant information
Name
Kobra Tahermanesh
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6435 2562
Email address
tahermanesh.k@iums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-21, 1400/02/01
Expected recruitment end date
2021-09-21, 1400/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of diluted ropivacaine in uterine distending fluid on pain after hysteroscopy surgeries

Public title
The effect of diluted ropivacaine in uterine distending fluid on pain after hysteroscopy surgeries

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women candidates for hysteroscopy treatment based on the opinion of a specialist Conscious consent to participate in the study
Exclusion criteria:
Existence of pelvic inflammatory disease Having known cervical malignancy, severe uterine bleeding, cervical conization Need for intraoperative surgery due to complications (such as laparotomy due to uterine perforation) Having psychological or neurological disorders that affect pain perception. Allergy to rupivacaine Reluctance to continue cooperation while studying Patients with chronic diseases with pain such as low back pain, etc. who use continuous painkillers. Patients have previously had a tubectomy or have a bilateral obstruction of the tube. Patients with preoperative pelvic pain, dyspareunia, dysmenorrhea, with a vas score of 3 or higher.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study with a sample size of 60 people, 30 balls for intervention group A and 30 balls for intervention group B are placed inside a lottery container and then the balls are randomly removed from the container without replacement, so a sequence is created.
Blinding (investigator's opinion)
Double blinded
Blinding description
The outcome assessor and data analyst will not know how the groups are assigned. We divide patients into two groups, A and B, and the outcome assessor and data analyzer identify the patient with A and B and do not know the nature of the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University Of Medical Sciences
Street address
Sattar Khan - Hazrat Rasool Akram Hospital
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2021-04-20, 1400/01/31
Ethics committee reference number
IR.IUMS.REC.1400.102

Health conditions studied

1

Description of health condition studied
Pain after hysteroscopic surgery in gynecological diseases
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intensity and frequency of pain
Timepoint
6, 12, 24 and 48 hours after hysteroscopy
Method of measurement
Questionnaire and patient file

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dilute rupivacaine (10 cc of half a percent rupivacaine per 1000 cc of normal saline per liter) is given as a dilating fluid during hysteroscopy.
Category
Treatment - Drugs

2

Description
Control group: They receive 10 cc of normal saline per 1000 cc of normal saline per liter as a dilating fluid during hysteroscopy.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Rasool Akram Hospital

Full name of responsible person
Dr Kobra Tahermanesh

Street address
Sattar Khan - Hazrat Rasool Akram Hospital

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 6650 9283

Email
tahermanesh.k@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr Seyed Abbas Motevalian-Vice President for Research of Iran University of Medical Sciences

Street address
Sattar Khan - Hazrat Rasool Akram Hospital

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 6650 9283

Email
tahermanesh.k@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
Kobra Tahermanesh

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Rasool-e Akram Hospital, Niayesh St., Sttarkhan St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 6435 2562

Fax
+98 21 6650 9283

Email
tahermanesh.k@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Kobra Tahermanesh

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Sattar Khan St., Maziar Mansouri St., Rasoul Akram Hospital

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 216651500

Email
tahermanesh.k@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Kobra Tahermanesh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Rasool-e Akram Hospital, Niayesh St., Sttarkhan St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 6435 2562
Fax
+98 21 6650 9283
Email
tahermanesh.k@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Part of data like the main outcome or the same will be shared
When the data will become available and for how long
Access after 6 months after publication
To whom data/document is available
Data will be available for all researchers
Under which criteria data/document could be used
It can be used for further research and improvement of surgery. Surgeons and gynecologists can use this data.
From where data/document is obtainable
For receiving data please be contacted with mehdizadeh.a@iums.ac.ir
What processes are involved for a request to access data/document
limitless
Comments