# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 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)
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**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

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## Sponsors / Funding sources

**1**

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Iran University of Medical Sciences

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Dr Seyed Abbas Motevalian-Vice President for Research of Iran University of Medical Sciences

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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**
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

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**Position**
Assistant Professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Gynecology and Obstetrics

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## Person responsible for updating data

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## 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**