

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Evaluating the pain-relief effect of different methods of local anesthesia in outpatient endometrial biopsy

Protocol summary

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Summary

The aim of this study is pain assessment of endometrial pipelle biopsy in patients receiving different methods of local anesthesia. One hundred sixty premenopausal women referring to Alzahra hospital and candidate for outpatient endometrial biopsy due to AUB will be recruited in a double blind clinical trial from 2011 to 2013. The patients will be randomly allocated to receive intrauterine injection of 5 ml 2% lidocaine, cervical spray of 3 puff lidocaine, 3 puff cervical spray of lidocaine plus intrauterine 5 cc of 2% lidocaine, or intrauterine injection of 5 cc distilled water, before biopsy. Primary outcome of this study is pain intensity which be compared between different groups.

Recruitment status

Recruitment complete

Funding source

Women's Reproductive Health Research Center, Vice Chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2011-02-20, 1389/12/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101135563N2**

Registration date: **2011-02-06, 1389/11/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-02-06, 1389/11/17

Registrant information

Name

Elaheh Ouladsahebmadarek

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1554 1221

Email address

Scientific title

Evaluating the pain-relief effect of different methods of local anesthesia in outpatient endometrial biopsy

Public title

Evaluating the pain-relief effect of different methods of local anesthesia in outpatient endometrial biopsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of AUB, no active uterine bleeding, willing to participate in the study, premenopausal women between 40-55 years, parity more than or equal to 1 Exclusion criteria: pregnancy, suspicious to PID, known cervical stenosis, known uncompensated cardio-pulmonary failure, active hepatic disease, allergy to lidocaine, no cooperation to pain assessment by VAS, chronic pelvic pain, nulliparity

Age

From **40 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

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

Tabriz University of Medical Sciences

Street address

Golgasht St.

City

Tabriz

Postal code

Approval date

2011-01-02, 1389/10/12

Ethics committee reference number

5/4/7975

Health conditions studied

1

Description of health condition studied

Abnormal uterine bleeding

ICD-10 code

N93.8

ICD-10 code description

Other specified abnormal uterine and vaginal bleeding

Primary outcomes

1

Description

Pain severity

Timepoint

during biopsy, immediately after biopsy, 15 min after biopsy

Method of measurement

visual analog scale

Secondary outcomes

1

Description

possible complications

Timepoint

during biopsy and after biopsy

Method of measurement

patient examination and questionnaire

Intervention groups

1

Description

Control group: receiving 5 ml distilled water intra uterus before biopsy.

Category

Placebo

2

Description

3 puffs lidocaine spray cervically 5 min before biopsy then 5 ml intra uterine 2% lidocaine solution 3 minutes before biopsy.

Category

Treatment - Drugs

3

Description

5 ml intra uterine 2% lidocaine solution 3 minutes before biopsy.

Category

Treatment - Drugs

4

Description

3 puffs lidocaine spray cervically 3-5 min before biopsy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Women's Reproductive Health Research Center,
Tabriz University of Medical Sciences

Full name of responsible person

Elaheh Ouladsahebmadarek

Street address

Alzahra Hospital, South Artesh Ave., Tabriz

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Women's Reproductive Health Research Center, Tabriz
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**

Tabriz University of Medical Sciences

Full name of responsible person

Elaheh Ouladsahebmadarek

Position

Associate Prof. of Ob & Gyn

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Elaheh Ouladsahebmadarek

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****Web page address****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