

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The priming effect of hyoscin on the cervix of non-pregnant married women before intrauterine procedures.

Protocol summary

Summary

: Uterine cervical firmness has been complained as the main barrier that prevents entering the endometrial cavity during the intrauterine procedures in cases such as endometrial curettage . Mechanical dilatation of cervical canal might cause uterine perforation, cervical tearing or incompetent cervix.Objective: In order to solve this problem, the researcher decided to substitute the mechanical intervention with chemical treatment by administration of Hyoscin to patients.

Design:Randomized, double blind, placebo controlled, phase 2 trial. Method: Sixty married nonpregnant women, 20-70 years of age, Including criteria: with cervical firmness who are scheduled for intrauterine procedure, because of gynecological diseases and Excluding criteria:they were not on hormonal therapy lately and they are not allergic to Hyoscin or having contraindication of Hyoscin usage will be randomly divided into two groups. Intervention: Group A, as experimental group, receives two doses of Hyoscin and group B, as control group, receives two doses of vitamin B6 in the posterior fornix of vagina (eight hours and two hours before the procedure) and the effects of these two drugs on Main outcome measure variables: dilatation and consistency of cervix will be studied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121312190N5**

Registration date: **2016-01-25, 1394/11/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Shiva Hadadian

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

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Phone

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Email address

shivahadadian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2015-12-20, 1394/09/29

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The priming effect of hyoscin on the cervix of non-pregnant married women before intrauterine procedures.

Public title

The effect of Hyoscin on the cervix of non-pregnant married women before curettage.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: women with gynecological diseases who were scheduled for curettage; Good general health; Want to participate in the study after it is explained; Increased endometrial thickness in sonography

evaluation or irregular endometrial echo in sonographic view; Uterine cervical firmness in examination. Exclusion Criteria: abundant vaginal bleeding; use of hormone replacement therapy lately; history of hypersensitivity to or contraindication of the Hyoscin usage.

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethical Committee of Shahid Beheshti University of Medical Science

Street address

Next to Ayatollah Taleghani Hospital, Yaman Street, Evin, Shahid Chamran High way, Tehran

City

Tehran

Postal code

198396-3113

Approval date

2015-12-01, 1394/09/10

Ethics committee reference number

lr.sbm.u.sm.rec.1394.82

Health conditions studied

1

Description of health condition studied

Uterine cervical firmness

ICD-10 code

XIV

ICD-10 code description

Diseases of the genitourinary system

Primary outcomes

1

Description

Uterine cervical dilatation

Timepoint

at the beginning of the study , then 2 hours after the second dose of the investigating drug.

Method of measurement

Budgie

2

Description

Uterine cervical consistency

Timepoint

at the beginning of the study , then 2 hours after the second dose of the investigating drug.

Method of measurement

passing number 2 Currett through uterine cervix and see its resistance

Secondary outcomes

1

Description

Tachykardia

Timepoint

2 hours after the second dose of the drug (at the beginning of the procedure)

Method of measurement

Questionnaire

2

Description

Uterine perforation

Timepoint

when the device passed through the cervical canal

Method of measurement

Examination

3

Description

Tearing of the uterine cervix

Timepoint

when the device passed through the cervical canal

Method of measurement

Examination

4

Description

Mouth dryness

Timepoint

2 hours after the second dose of the drug (at the beginning of the procedure)

Method of measurement

Questionnaire

5

Description

Nausea and vomiting

Timepoint

2 hours after the second dose of the drug (at the beginning of the procedure)

Method of measurement

Questionnaire

Intervention groups

1

Description

Control group: tablet 40 mg Vitamin B 6, vaginal, two doses, 8 hours and 2 hours before the procedure.

Category

Placebo

2

Description

Intervention group: tablet Hyoscin Butyl Bromide 10 mg , first dose 8 hours and the second dose 2 hours before the procedure, vaginally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sirjan dr Gharazi hospital

Full name of responsible person

dr Shiva Hadadian

Street address

Dr Gharazi hospital, shafa street

City

Sirjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Science.

Full name of responsible person

Dr Afshin Zarghi

Street address

Next to Ayatollah Taleghani hospital, Yaman street, Shahid Chamran highway

City

Tehran

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, Shahid Beheshti University of Medical Science.

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

Shahid Beheshti University of Medical Science

Full name of responsible person

Dr Shiva Hadadian

Position

Gynecologist and Obstetrician

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

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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