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
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Shahid Beheshti University of Medical Sciences
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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
Ir.sbmu.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 consistancy

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
Tackykardia

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 vomitting
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
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Person responsible for scientific inquiries

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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