Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessing the priming effect of Hyoscine instillation on the cervix of married women aged 20-70.

Protocol summary

Study aim
Assessing the priming effect of Hyoscine instillation on the unripe cervix of the nonpregnant women

Design
In this research, 30 eligible women who are candidates for intrauterine procedure and have closed cervix in primary examination are chosen and the intervention is done without randomization and control group.

Settings and conduct
Among the office patients, women who are candidate for intrauterine procedure and have a stenotic cervix are chosen and the researcher writes the information related to their primary examination of their cervix. Then she instills their cervix by 20 mg of hyoscin and after 10 minutes she measures their cervix dilatation with a maximum size dilator device which passes through the cervix hole.

Participants/Inclusion and exclusion criteria
Patients who are candidates of intrauterine procedure while having closed cervix; people who want to insert IUD for contraception but have a closed cervix are included to the study and people who have heart disease; peaple who take sympathetic stimulating medications; patients with hyperthyroidism; women who are allergic to Hyoscine are not included.

Intervention groups
patients, who are candidates of intrauterine procedure and have a closed cervix in their primary examination, are chosen and before the procedure, 20 mg of Hyoscine solution is poured on their cervix ostium and the size of cervical os reassessed after 10 minutes.

Main outcome variables
uterine cervix opening size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130119012190N6**
Registration date: **2018-01-26, 1396/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-26, 1396/11/06**
Update count: **0**

Registration date
2018-01-26, 1396/11/06

Registrant information

Name
Shiva Hadadian

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 23871

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shivahadadian@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-21, 1396/09/30

Expected recruitment end date
2018-04-03, 1397/01/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessing the priming effect of Hyoscine instillation on the cervix of married women aged 20-70.

Public title

Priming of the uterine cervix by Hyoscine instillation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women who are candidate for intrauterine procedure having closed cervix in primary examinnation

Exclusion criteria:

Heart disease Taking anticholinergic drugs Allergy to Hyoscin Hyperthyroidism

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Province

Tehran

Postal code

198396-3113

Approval date

2017-11-25, 1396/09/04

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.623

Health conditions studied

1

Description of health condition studied

closed cervix of the uterine

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

uterine cervix opening diameter

Timepoint

At the beginning of the study and ten minutes later.

Method of measurement

Dilator with maximum size

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Non pregnant women who are candidate of intrauterine procedure and they have a closed uterine cervix in examination are instilled in the cervix by 20 mg of Hyoscin, produced by Toliddaru company, which is an anticholinergic drug with anti spasm effect.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gharazi hospital

Full name of responsible person

Shiva Hadadian

Street address

Gharazi hospital, Shafa St., Malek Ashtar Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Afshin Zarghi

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

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Tehran

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1983969411

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Shiva Hadadian

Position
gynecologist and obstetrician

Latest degree
Specialist

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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data related to participants of the study are shareable after hiding their identities. Also protocol of study, study results, informed consent and statistical analysis plan are shareable.
When the data will become available and for how long
one month after announcing the results of study
To whom data/document is available
Academic people
Under which criteria data/document could be used
doing drug researches
From where data/document is obtainable
shivahadadian@yahoo.com Shiva Hadadian
What processes are involved for a request to access data/document
After expressing the purpose of needing the data via email and sending a letter showing that the they are used for scientific purposes, the data would be sent in one month.
Comments