Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Efficacy of sublingual misoprostol with sublingual misoprostol with laminaria on cervical dilation in the abortion rate from 4 to 14 weeks

Protocol summary

Summary

Objectives:Find a way to faster servicl ripening.Design:interventional.Setting and conduct: The two groups were matched in the first group of sublingual misoprostol 400µg 4 hours befor procedure and the intervention group to receive cervical laminaria plus 200µg sublingual misoprostol 4 hours before procedure.Inclusion criteria: 18 to 35 years ;gestational age less than 14 weeks;closed cervix;ultrasound consecutive Blighted Ovoum or Missed Abortion or the termination of pregnancy to order a forensic document. Exclusion criteria: medical conditions such as diabetes or high blood pressure or heart disease; surgery on the cervical area of the convention; women who take certain medications or an underlying allergy;Women who have vaginal bleeding at presentation ; women with a BMI of less than 20 or more than 25 ; more than 2 previous cesarean section; uterine anomalies .intervention:Misoprostol 400µg 4 hours befor procedure in the control group and misoprostol 200µg plus laminaria in the intervention group .The outcome of the investigation's achieving the desired cervical dilation or spontaneous expulsion of pregnancy products, pain intensity during waiting period, adverse effects of the ripening methods including nausea/vomiting, diarrhea, flashing and fever, post abortive infection and finally the patients' satisfaction at discharge

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070711020N4**
Registration date: **2015-07-24, 1394/05/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-24, 1394/05/02

Registrant information

Name
Maryam Khoshideh
Name of organization / entity
Tehran University of Medical Sciences, Arash Hospital
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Recruitment status

Recruitment complete

Funding source

Vice President of Medical Sciences, Tehran University of Medical Sciences

Expected recruitment start date

2015-07-24, 1394/05/02

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of sublingual misoprostol with sublingual misoprostol with laminaria on cervical dilation in the abortion rate from 4 to 14 weeks

Public title

Improving the effectiveness of misoprostol cervical ripening with laminaria

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 18 to 35 years ;gestational age less than 14 weeks;closed cervix;ultrasound consecutive Blighted Ovoum or Missed Abortion or the termination of pregnancy to order a forensic document. Exclusion criteria: medical conditions such as diabetes or high blood pressure or heart disease; surgery on the cervical area of the convention; women who take certain medications or an underlying allergy;Women who have vaginal bleeding at presentation ; women with a BMI of less than 20 or more than 25 ; more than 2 previous cesarean section; uterine anomalies .

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of Tehran University of Medical Science

Street address
Tehran University of Medical Science, Qods street

City
Tehran

Postal code

Approval date
2015-04-08, 1394/01/19

Ethics committee reference number
9111290040-144511

Health conditions studied

1

Description of health condition studied
Abortion

ICD-10 code
o04

ICD-10 code description
termination of pregnancy: legal therapeutic therapeutic abortion

Primary outcomes

1

Description
400µg sublingual misoprostol for cervical ripening

Timepoint
Every 4 hours

Method of measurement
≥Hegar7

2

Description
cervical ripening with:cervical laminaria plus 200µg sublingual misoprostol

Timepoint
Every 4 hours

Method of measurement
≥Hegar7

Secondary outcomes

1

Description
Symptoms of allergy to laminaria

Timepoint
every tow hours up to cervix prparation

Method of measurement
based on fever and Itching existance

2

Description
fever

Timepoint
every 2 hours up to preparation ofcervix

Method of measurement
Medical thermometer

Intervention groups

1

Description
Intervention group:receive cervical laminaria plus 200µg sublingual misoprostol 4 hours before procedure.

Category
Treatment - Other

2

Description
procedure Control group: sublingual misoprostol 400µg 4

hours befor procedure

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women 's Hospital

Full name of responsible person

Dr Maryam Khooshide

Street address

162 Alley, Rashid Aven,Resalat Hay wey

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences , Deputy of Research

Full name of responsible person

Dr. Akbar Fotohi

Street address

Qods St, Keshavarz Blvd

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 of Tehran University of Medical Sciences , Deputy of Research

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

Tehran University of Medical Sciences

Full name of responsible person

Dr Maryam Khooshide

Position

Associate professor

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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Nassim Yarmohammadi

Position

Gynecology Resident

Other areas of specialty/work

Street address

Arash Women 's Hospital 162 Alley, Rashid Aven,Resalat Hay wey

City

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Phone

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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