Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the results of using 25 µg sublingual misoprostol and Foley catheter together and each one alone in preparing cervix in low-term term pregnancies for termination of pregnancy with less than 4

Protocol summary

Summary

1) Objectives: The purpose of this study is to evaluate the benefits of sublingual misoprostol and Foley catheter and the simultaneous use of these two to achieve the best cervical preparation for termination of pregnancy. 2) Design: A one-way blind intervention will be conducted. 3) Setting & Conduct: Pregnant women with indication of termination of pregnancy will be randomly divided into 3 groups. The first group will receive only 25 µg sublingua misoprostol, the second group 25 µg sublingual misoprostol and foley catheter (30 mg normal saline) simultaneously, and the third group will receive only foley (30 mg normal saline). The amount of contractions in the uterus will be measured before intervention, 6, 12 and 18 hours after intervention. 4) Inclusion criteria: Pregnant women who indicate a termination of pregnancy (37-42 weeks); have normal delivery conditions: Cephalic presentation; women aged 18-45; urine score less than 4 Exclusion criteria: Abnormal heartbeat; Vaginal bleeding; Placenta praevia & Placental abruption; Multiple birth; Non-Cephalic presentation & Macrosomia; Infertility history greater than or equal to 6 years old and abnormal or fetal death; Multi-frequency higher than most 7; Rupture of Membeans; Intrauterine growth restriction and weighing over 4000 grams; History of uterine surgeries; tachycardia in mother; Preeclampsia; Abnormal liver and kidney tests. 5) Intrventions: The first group will receive only 25 µg sublingua misoprostol, the second group 25 µg sublingual misoprostol and foley catheter (30 mg normal saline) simultaneously, and the third group will receive only foley (30 mg normal saline). 6) main outcome measures (variables): Termination of pregnancy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072326695N2**
Registration date: **2017-07-31, 1396/05/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-31, 1396/05/09

Registrant information

Name
leila khayat zonuzi
Name of organization / entity
zaums
Country
Iran (Islamic Republic of)
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+98 22 2222
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l.zonuzi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the results of using 25 µg sublingual misoprostol and Foley catheter together and each one alone in preparing cervix in low-term term pregnancies for termination of pregnancy with less than 4

Public title
The effect of sublingual misoprostol and Foley catheter on termination of pregnancy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Pregnant women who indicate a termination of pregnancy (37-42 weeks); have normal delivery conditions: Cephalic presentation; women aged 18-45; urine score less than 4 Exclusion criteria: Abnormal heartbeat; Vaginal bleeding; Placenta praevia & Placental abruption; Multiple birth; Non-Cephalic presentation & Macrosomia; Infertility history greater than or equal to 6 years old and abnormal or fetal death; Multi-frequency higher than most 7; Rupture of Membeans; Intrauterine growth restriction and weighing over 4000 grams; History of uterine surgeries; tachycardia in mother; Preeclampsia; Abnormal liver and kidney tests
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Tehran, Iran
City
Tehran
Postal code
Approval date
2017-06-03, 1396/03/13
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.2489

Health conditions studied

1

Description of health condition studied
Delivery
ICD-10 code
O80-O84
ICD-10 code description
delivery

Primary outcomes

1

Description
Termination of pregnancy
Timepoint
Before intervention, 6 hours after intervention, 12 hours after intervention, 18 hours after intervention
Method of measurement
The amount of contractions of the womb

Secondary outcomes

empty

Intervention groups

1

Description
Group I: Sublingual misoprostol (25 µg)
Category
Other

2

Description
Group III: Foley catheter with 30 ml normal saline
Category
Other

3

Description
Group II: Sublingual misoprostol 25 µg and foley catheter (30 ml normal saline) simultaneously
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Yas Hospital
Full name of responsible person
Dr Leila Khayat zonuzi
Street address
Yas Hospital, North Nejatollahi st., Karimkhan Zand st.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Science
Full name of responsible person
Dr. Masoud Yoonesian
Street address
Central department of Tehran University of Medical Sciences, Intersection of Keshavarz blvd. and Qods St.
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, Tehran 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
Yas Hospital
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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