Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison the Effect of Isosorbide Mononitrate, Laminaria and Trans Cervical Catheter on cervical ripening and termination of term pregnancy

Protocol summary

Summary

The aim of this study is to investigate of the effects of Isosorbide mononitrate, laminaria and trans-cervical catheter on cervical ripening and terminating term pregnancy. Inclusion criteria included included the following: the Women with term pregnancy that are candidates for induction of labor, Bishop score is less than 4, Presentation of fetus is to be vertex and Nulliparous women. Exclusion criteria included the following: Having a spontaneous contraction and Rupture of membranes.The study population included of all nulliparous pregnant women with term pregnancy who will be referred for termination of pregnancy to the Kowsar hospital. Sample size would be 25 patients in each group. In Isosorbide mononitrate, 40 mg of this drug as Tablets will insert to the mother's vagina in Posterior Fornix. The dose can be repeated up to 3 times every 4 hours. The second and third doses, if Bishop is less than 4 per examination will be repeated every 4 hours. Administration of oxytocin immediately after preparation of the cervix or no response to procedures will be performed after 24 hours. In the trans-cervical catheter group, a Foley catheter will be used. Catheter through the cervix will be inserted into the internal orifice of the cervix and balloon with 30 cc of air will be filled. In Laminaria group, first, the maternal vagina will be cleaned with Bethadine. After the speculum inserted, the anterior lip of the cervix will be taken with tenaculum and laminaria will be taken down depending on the size of the cervix so that its tip has been diced near the internal opening of the cervix. the time between the onset of amniotomy or oxytocin administration to active phase; duration of first stage of labor; duration of the second stage of labor; duration of the third stage of labor; maternal complications (overstimulation of the uterus, postpartum hemorrhage, genital tract lacerations, headaches, nausea, vomiting, and dizziness); mode of delivery; neonatal outcomes (Apgar score at first and fifth minutes, sex and birth weight, hospitalization of neonate in the Neonatal Intensive Care Unit) will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012616368N1**
Registration date: **2014-02-22, 1392/12/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-22, 1392/12/03

Registrant information

Name

Maryam Iranipoor

Name of organization / entity

Qazvin University of Medical and Health Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Medicine school, Qazvin University of Medical Sciences and Health Services

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-02-28, 1392/12/09

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the Effect of Isosorbide Mononitrate, Laminaria and Trans Cervical Catheter on cervical ripening and termination of term pregnancy

Public title
cervical ripening and termination of term pregnancy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Women with term pregnancy that are candidates for induction of labor; Bishop score is less than 4; Presentation of fetus is to be vertex; Nulliparous women.Exclusion criteria: Having a spontaneous contraction; Rupture of membranes; Placenta previa.
Age
From **15 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **75**
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
Qazvin University of Medical Sciences and Health Services
Street address
Medicine School, Qazvin University of Medical Sciences and Health Services, Shahid Bahonar Boulevard
City
Qazvin
Postal code
Approval date
2013-09-04, 1392/06/13
Ethics committee reference number
28/20/7813

Health conditions studied

1

Description of health condition studied
Delivery
ICD-10 code
O00-O99
ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
cervical ripening
Timepoint
During at the study (every 4 hours)
Method of measurement
Examination of the vagina

Secondary outcomes

1

Description
Duration of the third stage of labor (from complete expulsion of fetus to the exit of placenta)
Timepoint
During at the study
Method of measurement
Observation and examination

2

Description
Method of Delivery
Timepoint
During at the study
Method of measurement
Observation and examination

3

Description
Maternal complications (Over stimulation of the uterus, postpartum hemorrhage, genital tract lacerations, headaches, nausea, vomiting, and dizziness)
Timepoint
During at the study
Method of measurement
Observation and examination

4

Description
Duration of first stage of labor (including latent and

active phases)

Timepoint

During at the study

Method of measurement

Observation and examination

5

Description

Duration of the second stage of labor (from full dilatation to expulsion of fetus)

Timepoint

During at the study

Method of measurement

Observation and examination

6

Description

Neonatal outcomes (Apgar score at first and fifth minutes, sex and birth weight, hospitalization of neonate in the Neonatal Intesive Care Uinte) will be measured

Timepoint

During at the study

Method of measurement

Observation and examination

Intervention groups

1

Description

In first group, Isosorbide Mononitrate, 40 mg of this drug as Tablets will insert to the mother's vagina in Posterior Fornix. The dose can be repeated up to 3 times every 4 hours. The second and third doses, if Bishop is less than 4 per examination will be repeated every 4 hours. Administration of oxytocin immediately after preparation of the cervix (Bishop more than 4) or no response to procedures will be performed after 24 hours.

Category

Treatment - Drugs

2

Description

In the second group, a Foley catheter will be used. Catheter through the cervix will be inserted into the internal orifice of the cervix and balloon with 30 cc of air will be filled.

Category

Treatment - Devices

3

Description

In third group, first, maternal vagina will be cleaned with Bethadine. After the speculum inserted, the anterior lip of the cervix will be taken with tenaculum and laminaria will be taken down depending on the size of the cervix so that its tip has been diced near the internal opening of the cervix.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Maryam Iranipoor

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences and Health Services

Full name of responsible person

Dr Saeid Asef Zadeh

Street address

Vice chancellor for research, Qazvin University of Medical Sciences and Health Services, Shahid Bahonar Boulevard, Qazvin

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin University of Medical Sciences and Health Services

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

Qazvin University of Medical Sciences and Health Services

Full name of responsible person

Maryam Iranipoor

Position

Resident of Obstetric and Gynecology

Other areas of specialty/work

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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