Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A comparison between the effect of Dilapan, extra amniotic normal saline infusion and oral misoprostol for cervical ripening in term pregnancies.

Protocol summary

Study aim

Comparison between the effect of Dilapan, extra amniotic normal saline infusion and oral misoprostol for cervical ripening in term pregnancies

Design

Simple, individual randomized clinical trial using sealed envelops on 120 term pregnant women

Settings and conduct

Not blind randomized clinical trial in Akbarabadi Teaching Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Parity 1, gestational age of 40-42 weeks, singleton, cephalic presentation, Bishop Score of less than 5 and age of less than 40 Exclusion criteria:ruptured membrane, history of using prostaglandins during pregnancy, previous uterine scare, allergy to prostaglandins, known asthma, and high diastolic blood pressure.

Intervention groups

In misoprostol group, 50 microgram misoprostol will be administered orally , after 6 hours, in the case of unripe cervix, the next 50 microgram misoprostol will be administered. After 12 hours, induction of labor with oxytocin will be started. In dilapan group, dilapan will be inserted in cervix for 6 hours and after 6 hours in the case of unripe cervix, dilapan will be remained in place. After 12 hours, dilapan will be removed and induction of labor with oxytocin will be started. In EASI group, a folly catheter will be inserted in the cervical canal and normal saline will be entered the extra amniotic space as 30 cc per hour. After 6 hours in the case of unripe cervix, EASI will be remained. After 12 hours, EASI will be removed and induction of labor with oxytocin will be started similar to the other groups.

Main outcome variables

Main outcome: duration up to cervical ripening (bishop score of 7 or more) Secondary outcomes: duration of the active phase and the second stage of labor, number of deliveries within the first 24 hours, interval between beginning of the intervention till delivery, rout of delivery, indications for cesarean , and uterine tachysystole.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091023002624N25**
Registration date: **2018-04-04, 1397/01/15**
Registration timing: **prospective**

Last update: **2018-04-04, 1397/01/15**
Update count: **0**

Registration date

2018-04-04, 1397/01/15

Registrant information

Name

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Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison between the effect of Dilapan, extra amniotic normal saline infusion and oral misoprostol for cervical ripening in term pregnancies.

Public title
3 methods of cervical ripening in term pregnancies.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnancy parity 1 gestational age of 40-42 weeks singletone cephalic presentation Bishop score of less than 5 age of less than 40
Exclusion criteria:
ruptured membrane history of using prostaglandine during present pregnancy previous uterine scare known asthma high diastolic blood pressure
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple, individual randomization using sealed envelops.
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 committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2018-01-02, 1396/10/12
Ethics committee reference number
IR.IUMS.REC.1396.31159

Health conditions studied

1

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

Primary outcomes

1

Description
duration up to cervical ripening (bishop score of 7 or more)
Timepoint
6 and 12 hours
Method of measurement
vaginal exam

Secondary outcomes

1

Description
En duration of the active phase of labor
Timepoint
En every 2 hours
Method of measurement
En vaginal exam

2

Description
duration of the second stage of labor
Timepoint
every 1 hours
Method of measurement
vaginal exam

3

Description
number of deliveries within the first 24 hours
Timepoint
After delivery
Method of measurement
Date sheet

4

Description
interval between beginning of the intervention till delivery
Timepoint
After delivery
Method of measurement
Data sheet

5

Description
rout of delivery
Timepoint
After delivery
Method of measurement
Data sheet

6

Description
indications for cesarean
Timepoint
After delivery
Method of measurement
Data sheet

7

Description
uterine tachysystole
Timepoint
during labor
Method of measurement
tocography

Intervention groups

1

Description
Intervention group: In misoprostol group, 50 microgram misoprostol will be administered orally , then cervix will be checked for Bishop Score after 6 hours.In the case of unripe cervix, the next 50 microgram misoprostol will be administered. After 12 hours, induction of labor with oxytocin will be started.
Category
Treatment - Drugs

2

Description
Intervention group: In dilapan group, dilapan will be inserted in cervix for 6 hours and after 6 hours cervix will be checked for Bishop Score and in the case of unripe cervix, dilapan will be remained in place. After 12 hours, dilapan will be removed and induction of labor with oxytocin will be started.
Category
Treatment - Drugs

3

Description
Intervention group: In EASI group, a folly catheter will be inserted in the cervical canal and normal saline will be entered the extra amniotic space as 30 cc per hour. After 6 hours cervix will be checked for Bishop Score and in the case of unripe cervix, EASI will be remained. After 12 hours, EASI will be removed and induction of labor with oxytocin will be started similar to the other groups.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi Hospital
Full name of responsible person
Maryam Kashanian
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Molavi street, Molavi cross
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr SeyedKazem Malakooti
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Iran 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
Iran University of Medical Sciences

Full name of responsible person
Maryam Kashanian

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Position
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Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Presenting at a paper, congress or seminars.

When the data will become available and for how long
After publication of the paper.

To whom data/document is available
Iran University of Medical Sciences

Under which criteria data/document could be used

Permission from Iran University of Medical Sciences

From where data/document is obtainable

From Iran University of Medical Sciences

What processes are involved for a request to access data/document

Request from Iran University of Medical Sciences.

Comments