

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 envelopes 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

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 3487

Email address

maryamka@iums.ac.ir

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

۱۴۳۹۶۱۴۵۳۵

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

route 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 Foley 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

Street address

Molavi street, Molavi cross

City

Tehran

Province

Tehran

Postal code

۱۱۶۸۷۴۳۵۱۴

Phone

+98 21 5563 3244

Email

maryamkashanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr SeyedKazem Malakooti

Street address

Hemmat Highway, Chamran Cross

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

PR@iums.ac.ir

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
Street address
 Molavi street, Molavi Cross
City
 Tehran
Province
 Tehran
Postal code
 ۱۱۶۸۷۴۳۵۱۴
Phone
 +98 21 5563 3244
Fax
 +98 21 5560 8012
Email
 maryamka@iums.ac.ir

Person responsible for scientific 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
Street address
 Molavi street, Molavi Cross
City
 Tehran
Province
 Tehran
Postal code

۱۱۶۸۷۴۳۵۱۴

Phone
 +98 21 5563 3244
Fax
 +98 21 5660 8012
Email
 maryamka@iums.ac.ir

Person responsible for updating data

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
Street address
 Molavi street, Molavi Cross
City
 Tehran
Province
 Tehran
Postal code
 ۱۱۶۸۷۴۳۵۱۴
Phone
 +98 21 5563 3244
Fax
 +98 21 5660 8012
Email
 maryamka@iums.ac.ir

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