Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Efficacy and side effects of transcervical catheter and vaginal Misoprostol on cervical ripening

Protocol summary

Summary

When labor induction is indicated for women with unripe cervix and oxytocin induction alone will not be answered, there is severel choices for ripening of cervix with low bishop score. Transcervical catheter and misoprostol are kinds of them.This research will compare benefits and disadvantages of this two procedures.Term pregnant women with indication of delivery and low bishop score of cervix divide to same 60 groups of getting misoprostol or transcervical catheter and then evaluate time of ripening of cervix,c/s rate,and other disadvantages such as meconium in amnionic fluid.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012225448N1**
Registration date: **2011-05-04, 1390/02/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-05-04, 1390/02/14

Registrant information

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Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences, Research Chancellory

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-10-23, 1390/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and side effects of transcervical catheter and vaginal Misoprostol on cervical ripening

Public title

The comparison of drug and mechanical methods for cervical ripening before delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:gestatinal age over 37 weeks, singleton gestation,cephalic presentation, intact amnion sac,not contraindication of misoprostol use,first gravity ,3 to 4 bishop score Exclusion criteria:allergy to misoptostol,elective cesarean section,urgent delivery by c/s,IUGR,placenta previa,fetal bradycardia, placenta abruption,massive bleeding ,placenta previa and previous cesarean section.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **120**

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
Tabriz University Of Medical Sciences,Vice chancellor for Research

Street address
Third Floor, Central Building of Number2, Golgasht Street

City
Tabriz

Postal code

Approval date
2010-10-09, 1389/07/17

Ethics committee reference number
5/4/6866

Health conditions studied

1

Description of health condition studied
Ripening Of Cervix

ICD-10 code
O60-O75

ICD-10 code description
Complications of labour and delivery

Primary outcomes

1

Description
Ripening of cervix

Timepoint
in the time of intervention

Method of measurement
bishop score

Secondary outcomes

1

Description
Meconium In Amnionic Fluid

Timepoint
at time of intervention

Method of measurement
Clinical

2

Description
Uterine Hyperstimulation

Timepoint
at time of intervention

Method of measurement
clinical

3

Description
Rupture of uterin

Timepoint
at time of intervention

Method of measurement
clinical

4

Description
Result in c/s

Timepoint
at time of intervention

Method of measurement
Clinical

5

Description
Fetal Bradycardia

Timepoint
In the time of intervention

Method of measurement
Clinical

Intervention groups

1

Description
Misoprostol 25 microgram per 8 hour until 3 doses will be used in 60 patients with the cervix bishop score 3 or 4. Then duration time to reach 8 bishop score will be measured.

Category
Treatment - Other

2

Description
On the other 60 ones with cervix bishop score of 3or4,

transcervical catheter will be used. time of receiving to cervix bishop score of 8 will be evaluated.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital-Tabriz and Alzahra Hospital Tabriz

Full name of responsible person

Dr.Fatemeh Mallah

Street address

Taleghani Hospital, Rah Ahan Square

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University Of Medical Sciences، Vice chancellor for Research

Full name of responsible person

Dr. Alireza Ostad Rahimi

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University Of Medical Sciences، Vice chancellor for 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

Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Fatemeh Mallah

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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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