Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the effect of misoprostol and cervical catheter with oxytocin and cervical catheter in the induction of labor: a clinical trial

Protocol summary

Study aim
Comparison of the effect of misoprostol and cervical catheter with oxytocin and cervical catheter in the induction of labor

Design
This randomized double-blind clinical trial study will be performed on 50 patients undergoing induction of labor with a computer-generated randomization list with a block size of 4, with 1:1 allocation.

Settings and conduct
Term pregnant women admitted to al-Zahra and Taleghani hospitals in Tabriz who are candidates for termination of pregnancy through vaginal delivery due to various reasons are included in this study. First, we will take informed written consent and all part of the study will be explained to the patients. The treatment allocation will be placed in a sealed opaque envelope and picked up consecutively.

Participants/Inclusion and exclusion criteria
inclusion criteria: term pregnancy, indication for termination of pregnancy, Bishop Score 6 or less, singleton pregnancy, reassuring fetal heart rate, cephalic presentation, intact fetal membranes, ineffective labor contractions, primiparous women exclusion criteria: Misoprostol allergy, fever over 38 °C, history of uterine and cesarean surgery, obstetric induction for cesarean delivery, anemia and blood dyscrasia and asthma

Intervention groups
In the misoprostol and catheter group, a no.16 foley catheter is inserted into the cervix and at the same time 25 µg misoprostol is given sub-lingually and if there is no any contraction repeated every 6 hours for up to 4 doses. In the second group, the cervical catheter is inserted and induction begins with oxytocin. In both groups, the Foley catheter balloon is filled with 30 ml of distilled water.

Main outcome variables
Time needed to soften and ripen the cervix

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101227005485N8**
Registration date: **2020-04-27, 1399/02/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-27, 1399/02/08**
Update count: **0**

Registration date
2020-04-27, 1399/02/08

Registrant information

Name
Nazli Navali

Name of organization / entity
Tabriz University of Medical Sciences, Faculty of Medecine

Country
Iran (Islamic Republic of)

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+98 41 1330 2879

Email address
navalin@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-08-20, 1399/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of misoprostol and cervical catheter with oxytocin and cervical catheter in the induction of labor: a clinical trial

Public title
Comparison of the effect of misoprostol with oxytocin in companion with a cervical catheter in the induction of labor: a clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnancy age of 37 weeks and over indication for termination of pregnancy primiparous women singleton pregnancy reassuring fetal heart rate cephalic presentation intact fetal membranes ineffective labor contractions Bishop Score 6 or below

Exclusion criteria:
Misoprostol allergy fever over 38 °C history of uterine surgery and cesarean obstetric indication for cesarean delivery anemia and blood dyscrasia asthma

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The placement in each intervention or control group will be done by the sealed envelopes containing the type of intervention and the envelopes will be removed and opened consecutively, and the type of treatment will be based on its content. This will be done in such a way that the outcome assessor and the data analyzer will not know the intervention type.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical

Street address
Research Deputy of Tabriz University of Medical Sciences, University of Tabriz, Golgasht street

City
Tabriz

Province
East Azarbaijan

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2019-12-24, 1398/10/03

Ethics committee reference number
IR.TBZMED.REC.1398.984

Health conditions studied

1

Description of health condition studied
labor induction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The time to ripen the cervix

Timepoint
every two hours

Method of measurement
vaginal examination

2

Description
Duration of latent phase of labor

Timepoint
every two hours

Method of measurement
vaginal examination

Secondary outcomes

1

Description
Duration of active phase of labor

Timepoint
every hour

Method of measurement
vaginal examination

2

Description

duration of second stage of labor

Timepoint

every half hour

Method of measurement

vaginal examination

3

Description

complication rate

Timepoint

Continuous during labor

Method of measurement

fetal monitoring

Intervention groups

1

Description

Control group:Following the insertion of the Foley catheter No.16 inside the uterus and filling its bag with 30 cc of serum saline, 25 micro-gram of misoprostol tablet will be given sub-lingually and repeated every 6 hours for up to 4 doses in the absence of effective labor contractions. If spontaneous contractions occur for at least 3 contractions of 45-60 seconds within 10 minutes, the next dose will not be given. Upon dilatation of 3–4 cm, if no contraction occurs, induction will begin with high dose oxytocin (4 mili-unit per minute every 15-20 minutes will be done and this will be continued until at least 3-4 contractions of 45-60 seconds occur every 10 minutes) method.

Category

Treatment - Drugs

2

Description

Intervention group: Following the insertion of the Foley catheter No.16 inside the uterus and filling its bag with 30 cc of serum saline, induction with high dose method, 4 mili-unit per minute of oxytocin and increment of 4 mili-unit per minute every 15-20 minutes will be done and this will be continued until at least 3-4 contractions of 45-60 seconds occur every 10 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra and Taleghani Hospitals

Full name of responsible person

Dr. Navali Nazli

Street address

South Artesh Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3554 1221

Email

navalin@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Laya Farzadi

Street address

South Artesh Street

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5138665793

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Email

navalin@tbzmed.ac.ir

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

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

Tabriz University of Medical Sciences

Full name of responsible person

Nazli Navali

Position

infertility fellowship/associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Alzahra hospital, Artesh street
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Postal code
5138665793
Phone
+98 41 3554 1221
Email
navalin@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Nazli Navali
Position
associate professor/infertility fellowship
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Nazli Navali
Position
associate professor/infertility fellowship
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be 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
Part of the data will be published as an article.
When the data will become available and for how long
2 years
To whom data/document is available
The data will be accessible to anyone interested in the field.
Under which criteria data/document could be used
for utilization in researches like in metha-analyses
From where data/document is obtainable
The applicants can mail there request to the person responsible for scientific inquiries or by referring to Women's Health Research Center, Al-Zahra Hospital, Artesh street in Tabriz, they ask the scientific staff to study the data and mention their motives.
What processes are involved for a request to access data/document
After requesting the data via email, after reviewing the motivation and purpose of the request, the data will be made available to the applicant.
Comments