Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of simultaneous administration of oxytocin with Foley catheter with co-administration of misoprostol and Foley catheter on cervical preparation and duration of labor in extended pregnancies.

Protocol summary

Study aim

Comparison of the effect of simultaneous administration of oxytocin with Foley catheter with co-administration of misoprostol and Foley catheter on cervical preparation and duration of labor

Design

This study is clinical trial which will be conducted on 74 pregnant women. In both groups, during labor, fetal heat beat and uterine contractions are monitored. General information on patients such as age, BMI, gestational age, indication of termination of pregnancy are entered in the self made questionnaire and afterwards, the primary outcome including cervix Bishop Score after 24 hours is then recorded every 4 hours until reaching Bishop Score of 7 (cervix is ready) and compared in both groups.

Settings and conduct

No blinding is done and patients admitted in Ommol-Banin, Ghaem and Imam Reza Hospitals in Mashhad enter the study in 2 groups using simple randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria : alive singleton pregnancy; gestational age of equal to or greater than 40 weeks; cephalic presentation; absence of fetal anomaly; Bishop Score of less than 4; mother's age is greater than 18; absence of medical illnesses such as diabetes and high blood pressure. Exclusion criteria : placental abruption; chorioamnionitis; rupture of the membrane before the catheter is excreted; previous Cesarean section; Placenta Previa.

Intervention groups

Intervention group: simultaneous with placing Foley catheter, administration of oxytocin with dosage of 2 milliunits/min and addition of 2 milliunits every 20 minutes up to reaching a maximum of 30 milliunits/min. Control group: simultaneous with placing Foley catheter, sublingual misoprostol with dosage of 25 micro grams per every 4 hour up to a maximum of 6 dosages is prescribed.

Main outcome variables

Duration of reaching Bishop Score of 7 (cervix is ready) during 24 hours, is recorded every 4 hours.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181123041731N2**
Registration date: **2019-06-26, 1398/04/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-26, 1398/04/05**
Update count: **0**

Registration date

2019-06-26, 1398/04/05

Registrant information

Name

Malihe Rakhshani Far

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2861

Email address

rakhshanifm951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of simultaneous administration of oxytocin with Foley catheter with co-administration of misoprostol and Foley catheter on cervical preparation and duration of labor in extended pregnancies.

Public title
Comparison of the effect of simultaneous administration of oxytocin with Foley catheter with co-administration of misoprostol and Foley catheter on cervical preparation and duration of labor
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Alive singleton pregnancy Gestational age of equal to or greater than 40 weeks Cephalic presentation Absence of fetal anomaly Weight estimate of the fetus is less than 4500 grams Bishop Score of less than 4 Mother's age is greater than 18 Absence of parity of over 5 Absence of medical illnesses such as diabetes and high blood pressure
Exclusion criteria:
Placental abruption Chorioamnionitis Rupture of the membrane before the catheter is excreted Previous Cesarean section Gestational diabetes Placenta Previa and any type of contraindication for vaginal bleeding
Age
From **18 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization is carried out using table of random numbers with the help of "www.randomization.com" website in which numbers are placed in sealed envelopes and once patients enter the study, envelopes are allocated to them placing them in one of the 2 groups.
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 Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi),Daneshgah 16, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2019-04-09, 1398/01/20
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.119

Health conditions studied

1

Description of health condition studied
extended pregnancies
ICD-10 code
O66.9
ICD-10 code description
Obstructed labor, unspecified

Primary outcomes

1

Description
Duration of reaching Bishop Score of 7 (the cervix is ready)
Timepoint
4 every 4 hours
Method of measurement
Internal examination

Secondary outcomes

1

Description
Duration of delivery
Timepoint
From admission to delivery
Method of measurement
Based on patient's file

2

Description
Delivery method
Timepoint
At the time of delivery
Method of measurement
Based on the type of delivery which is recorded in the patient's file

3

Description
Labor complications including tachysystole (more than 5 contractions in 10 minutes), bleeding after delivery
Timepoint
After delivery
Method of measurement
Clinical observation

Intervention groups

1

Description
Intervention group: immediately after placing the Foley catheter, administration of oxytocin with dosage of 2 milliunits/min begins and 2 milliunits are added every 20 minutes up to reaching a maximum of 30 milliunits/min. After excretion of catheter in the active phase (dilation of 6 centimeters) and in case of the head being fixed, amniotomy is carried out.
Category
Treatment - Drugs

2

Description
Control group: After embedding the Foley catheter, sublingual misoprostol with dosage of 25 micro gram per every 4 hour up to a maximum of 6 dosages is prescribed. In this group, also, after excretion of catheter in the active phase (dilation of 6 centimeters) and in case of the head being fixed, amniotomy is carried out.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Malihe Rakhshani Far
Street address
Ghaem hospital, Ahmad Abad Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3801 2477
Email
Rakhshanifm951@mums.ac.ir

2

Recruitment center
Name of recruitment center
Ommol-Banin hospital
Full name of responsible person
Masoumeh Mirteimouri
Street address
Ommol-Banin hospital, Azadi 16th, Azadi Avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9144663595
Phone
+98 51 3223 1444
Email
mirteimourim@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 2081
Email
ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Rakhshani Far

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Ghaem hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2477

Email

rakhshanifm951@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Masoumeh Mirteimouri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Ommol-Banin hospital, Azadi 16th, Azadi Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9144663595

Phone

+98 51 3223 1444

Email

mirteimourim@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Rakhshani Far

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Ghaem hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2477

Email

Rakhshanifm951@mums.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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

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

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments