Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of oral and vaginal isosorbide mononitrate and oral propranolol tablets on cervical preparation before induction in primiparous and term pregnancy

Protocol summary

Study aim

Evaluation of oral and vaginal tabletsisosorbide mononitrate and oral propranolol tablets for Preinduction of Cervical Ripening in primiparous term pregnancy

Design

Clinical trial with control group, one-blind, randomized, phase three on 120 patients. Excel software rand function was used for randomization

Settings and conduct

In a randomized single-blind randomized clinical trial 120 pregnant women of normal term with normal pregnancy and with a score of 2 or less who were referred to Yas Hospital in Tehran were selectedand were randomly divided into four groups by random allocation.The intervention groups did not know the type of drug. Intervention groups included a group of vaginal isosorbide mononitrate(40 mg), one group of oral isosorbide mononitrate(40 mg), one group of oral propranolol tablets(20 mg), and one control group without The intervention .Cervical maturation was measured before and 24 hours after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 37-40 weeks gestation،primiparous, live fetus,single fetus, cephalic, intact membranes ,Bishab score under two, fetal weight less than 4 kg. Exclusion criteria: History of headache, alcohol , preeclampsia ,IUGR, polyhydramnios and oligohydramnius, placenta previa

Intervention groups

Intervention groups included a group of vaginal isosorbide mononitrate (40 mg), one group of oral isosorbide mononitrate (40 mg) , one group of oral propranolol tablets (20 mg) and one control group without The intervention 30 people was measured.

Main outcome variables

Method of delivery, time elapsed to dilation 6cm Duration elapsed time from dilatation 6 cm to full dilation, Time elapsed from full dilation to delivery, Maternal complications, Bishop score change 24 hours after receiving the drug, Apgar 5 min, Cord pH, NICU hospitalization, meconium excretion, need for oxytocin to induce labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201003048910N1**
Registration date: **2020-10-18, 1399/07/27**
Registration timing: **retrospective**

Last update: **2020-10-18, 1399/07/27**
Update count: **0**

Registration date

2020-10-18, 1399/07/27

Registrant information

Name

Mahnaz Tajpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2278 5738

Email address

mahnaz_tajpour@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date
2018-09-30, 1397/07/08
Actual recruitment end date
2019-10-22, 1398/07/30
Trial completion date
2019-10-22, 1398/07/30

Scientific title
Evaluation of the effect of oral and vaginal isosorbide mononitrate and oral propranolol tablets on cervical preparation before induction in primiparous and term pregnancy

Public title
Evaluation of the effect of oral and vaginal isosorbide mononitrate tablets and oral propranolol tablets on cervical preparation.
Purpose
Screening
Inclusion/Exclusion criteria
Inclusion criteria:
Includes 37-40 weeks gestation live fetus Noli Par single fetus cephalic intact membranes under two bishop scores fetal weight less than 4 kg normal fetal health monitoring result no uterine contractions There were no systemic problems in the history and clinical examination.
Exclusion criteria:
Abnormality of fetal appearance with pelvis or non-cephalic presence of uterine scar previous history of cesarean section history of cervical cone (conization) polyhydramnios history of drug allergy contraindications to vaginal delivery aginal bleeding during third trimester placenta previa multiple pregnancy suspected fetal abnormality bishop score above 3 uterine contractions uncertain NST chorioamnionitis history of asthma active genital herpes any contraindications to induction of labor systolic pressure less than 90 Cardiovascular disease severe preeclampsia alcoholism history of headache
Age
From **21 years** old to **30 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **120**
Actual sample size reached: **120**
More than 1 sample in each individual
Actual sample size in each individual: **30**
The sample size was determined based on statistical formulas and 95% confidence level, 120 people, 30 people were considered for each group.
Randomization (investigator's opinion)
Randomized
Randomization description
The primiparous term pregnancy who needed induction of labor due to termination of pregnancy and adverse cervix were easily selected and based on a random number table into four groups of recipients of forty mg isosorbide vaginal mononitrate (n = 30) and oral isosorbide mononitrate. Forty mg (30) patients and 40 mg oral propranolol tablets (two 20 mg tablets every twelve hours to the dose (n = 30) and the control group (n = 30) were divided.
Blinding (investigator's opinion)
Single blinded
Blinding description
The person assessing the consequences is kept blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research, School of Medicine, Tehran University of Medical Sciences
Street address
No18,deldar,baradaran rahmani avenu,sadr blv
City
Tehran
Province
Tehran
Postal code
1939963559
Approval date
2019-12-07, 1398/09/16
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.641

Health conditions studied

1

Description of health condition studied
cervical ripening
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
cervical ripening
Timepoint
24 hours after the start of the study
Method of measurement
vaginal examination

Secondary outcomes

1

Description
Duration of the first phase of labor (including latent and active phase)
Timepoint
During the study
Method of measurement
Observation and examination

2

Description
Duration of the second stage of labor (from complete dilatation to fetal delivery)
Timepoint
During the study
Method of measurement
Observation and examination

3

Description
Duration of the third stage of labor (from the time of embryo departure to complete placental abruption)
Timepoint
During the study
Method of measurement
Observation and examination

4

Description
Method of childbirth
Timepoint
During the study
Method of measurement
Observation and examination

5

Description
Maternal complications (headache, nausea, vomiting and dizziness)
Timepoint
During the study
Method of measurement
Observation and examination

6

Description
Neonatal outcomes (first and fifth minute Apgar score, umbilical cord PH, neonatal hospitalization in intensive care unit)
Timepoint
During the study
Method of measurement
Observation and examination

Intervention groups

1

Description
In the first group, single dose of 40 mg of isosorbide mononitrate from Aria drug will be placed vaginally in the posterior fornix by the researcher.
Category
Treatment - Devices

2

Description
In the second group single dose of 40 mg Isosorbide mononitrate tablets are given orally from Aria Pharmaceutical Company.
Category
Treatment - Devices

3

Description
Oral propranolol tablets are given orally at single dose of 20 mg from Dr. Obidi Pharmaceutical Company.
Category
Treatment - Devices

4

Description
Control group: The control group is given 24 hours to soften the cervix and no medication is prescribed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Yas Comprehensive Women's Hospital
Full name of responsible person
Mahnaz Tajpour
Street address
Karim Khan, North Villa
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1939963559
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
drug
Proportion provided by this source
10
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahnaz Tajpour
Position
resident
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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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

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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