Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

A comparison between misoprostol plus propranolol and misoprostol alone in labour induction (in post term pregnancies.)

Protocol summary

Summary

Objective: A comparison between misoprostol plus propranolol and misoprostol alone in labour induction (in post term pregnancies.) Design: Randomized, (clinical trial) , Double blind, placebo-controlled, Academic maternity hospitals Participants: Pregnant women with post term pregnancy Inclusion criteria: nulliparous women with Gestational age more than 41 weeks ؛ Single pregnancy؛ Cephalic presentation؛ Bishop score<5؛ indication for the induction of delivery؛ admitted in academic hospitals Exclusion criteria: Pregnant women with uterus contraction؛ fetal distress؛ Suspected macrosomia؛ Polyhydroamnius؛ Systolic blood pressure less than 100mmHg؛ Pulse rate less than 60 and more than 120؛ Any history of cardiopulmonary disease ؛alcohol abuse. sample size: 80 Intervention: prescription of propranolol in pregnant women with indication for the induction of delivery Intervention Time: At the beginning of labour induction The outcome of the study: The time lapse from the beginning of induction to effective contractions Other outcomes: the time lapse from the beginning of induction to 4cm dilatation, the time lapse from the beginning of induction to delivery, the neonatal outcomes such as Apgar score and NICU admission, cesarean rate

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110530709N1**
Registration date: **2016-12-18, 1395/09/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-12-18, 1395/09/28

Registrant information

Name

Atiyeh Mohamadzade Vatanchi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2477

Email address

vatanchia@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between misoprostol plus propranolol and misoprostol alone in labour induction (in post term pregnancies.)

Public title

propranolol effect on pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: nulliparous women with Gestational age more than 41 weeks ؛ Single pregnancy؛ Cephalic presentation؛ Bishop score<5؛ indication for the induction of delivery؛ admitted in academic hospitals

Exclusion criteria: Pregnant women with uterus contraction؛ fetal distress؛ Suspected macrosomia؛ Polyhydroamnius؛ Systolic blood pressure less than 100mmHg؛ Pulse rate less than 60 and more than 120؛ Any history of cardiopulmonary disease ؛alcohol abuse.

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Building Qureshi, Daneshgah street, Taghi Abad

City
Mashhad

Postal code

Approval date
2016-08-17, 1395/05/27

Ethics committee reference number
IR.MUMS.fm.REC.1394.89

Health conditions studied

1

Description of health condition studied
Labour induction

ICD-10 code
o61

ICD-10 code description
Failed induction of labour

Primary outcomes

1

Description
The time of begining of effective contractions

Timepoint
Before Intervention and after effective contractions

Method of measurement
minute

Secondary outcomes

1

Description
The time lapse from the beginning of induction to 4cm dilatation

Timepoint
before intervention and at the time of 4cm dilatation

Method of measurement
minute

2

Description
The time lapse from the beginning of induction to delivery

Timepoint
before intervention and at the time of delivery

Method of measurement
minute

3

Description
Neonatal Apgar score

Timepoint
At the first and the fifth minutes after birth

Method of measurement
Apgar scale

4

Description
Neonatal NICU admission

Timepoint
The first day after the birth

Method of measurement
Questionnaire

5

Description
Cesarean rate

Timepoint
Birth time

Method of measurement
Questionnaire

Intervention groups

1

Description
The Intervention group recieve 20mg Propranolol tablet concurrent with sublingual Misoprostol at the begining of induction. If there is no effective contraction, the dose will be repeated after 3 hours.
Category
Treatment - Drugs

2

Description
The Control group recieve oral Placebo tablets that their shape, color and weight are similar to 20mg propranolol tablets, in the same way of the intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Qaem Hospital
Full name of responsible person
Atiyeh Mohamadzade Vatanchi
Street address
City
Mashhad

2

Recruitment center
Name of recruitment center
Ommol-banin Hospital
Full name of responsible person
Leila Pourali
Street address
City
Mashhad

3

Recruitment center
Name of recruitment center
Imam Reza (a.s.) Hospital
Full name of responsible person
Sedighe Ayati
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Council of Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Mashhad School of Medicine, Pardis University, Azadi Square, Mashhad
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Council of Mashhad University of Medical Sciences
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
Mashhad University of Medical Sciences
Full name of responsible person
Atiyeh Mohamadzade Vatanchi
Position
assistant professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Phone
00
Fax
Email
Web page address

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