

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: Polyhydroamnios: 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 receive 20mg Propranolol tablet concurrent with sublingual Misoprostol at the beginning of induction. If there is no effective contraction, the dose will be repeated after 3 hours.

Category

Treatment - Drugs

2

Description

The Control group receive 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 Pournali

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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Mashhad University of Medical Sciences

Full name of responsible person

Atiyeh Mohamadzade Vatanchi

Position

assistant professor

Other areas of specialty/work**Street address**

Ghaem hospital

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