

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison the effect of oral propranolol and oxytocin with oxytocin alone on duration of labor and type of delivery in nulliparous women with prolonged pregnancy.

Protocol summary

Summary

Introduction: prolonged pregnancy increases the maternal morbidity and fetal morbidity and mortality. In order to avoid these complications and to manage prolonged pregnancies, different methods are used. The purpose of this study was comparison the effect of oral propranolol and oxytocin with oxytocin alone on duration of labor and type of delivery in nulliparous women with prolonged pregnancy. Material and Methods: A double blind randomized controlled trial was performed on 146 nulliparous; 18-35 years; gestational age 40-42 weeks; without CPD; bishop score less than 5; optimal care during pregnancy; blood pressure less than 140/90 mmHg; pulse 60-110; body mass index normal; intact of membran; estimated fetal weight less than 4000 grams; Excluding criteria: Polyhydramnios; abnormal presentation; preeclampsia; known medical conditions before and during pregnancy such as asthma; cardiovascular and metabolic disease at the admission time. After accurate determination of pregnancy age the patients were classified into two groups of a combination of oral propranolol and oxytocin versus oxytocin only. In the first group (oxytocin group=73), oxytocin alone was used for induction of labor. In the second group (propranolol group=73 cases), oral propranolol 20 mg was prescribed then the induction was began. Induction was similar in both groups using low dose method. The mean duration for obtaining good contractions, first and second stages, type of delivery and apgar scour was determine and statistical analysis was performed using spss software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105316575N3**

Registration date: **2011-07-23, 1390/05/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-23, 1390/05/01

Registrant information

Name

Ashraf Direkvand-Moghadam

Name of organization / entity

Ilam University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ilam University of Medical Sciences

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2009-09-23, 1388/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of oral propranolol and oxytocin

with oxytocin alone on duration of labor and type of delivery in nulliparous women with prolonged pregnancy.

Public title

Comparison the effect of oral propranolol and oxytocin with oxytocin alone on duration of labor and type of delivery in nulliparous women with prolonged pregnancy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 35-18 years of age; primiparous; singleton pregnancy; gestational age 40-42; without CPD; Bishop score less than 5; optimal care during pregnancy; blood pressure less than 140/90 mmHg; pulse 60-110; body mass index 19/8-26(kg/m) before pregnancy; intact of membran; estimated fetal weight less than 4000 grams; Excluding criteria: Polyhydramnios; abnormal presentation; preeclampsia; known medical conditions before and during pregnancy such as asthma; cardiovascular and metabolic disease at the admission time

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Ilam University of Medical Sciences

Street address

Ilam University of Medical Sciences

City

Ilam

Postal code

Approval date

2008-05-24, 1387/03/04

Ethics committee reference number

2039/40/22

Health conditions studied

1

Description of health condition studied

The effect of oral propranolol on the duration of labor and type of delivery in nulliparous women with prolonged pregnancy.

ICD-10 code

o48

ICD-10 code description

Prolonged pregnancy

Primary outcomes

1

Description

Duration of labor in nulliparus women with prolonged pregnancy

Timepoint

Start of admission in hospital to 24h after delivery

Method of measurement

Duration of labor according to minute

Secondary outcomes

1

Description

Type of delivery

Timepoint

Start of admission in hospital to 24h after delivery

Method of measurement

Type of delivery vaginal or cesarean

Intervention groups

1

Description

The first group: induction was performed with low dose method

Category

Treatment - Drugs

2

Description

The second group: 20 mg propranolol was administered orally then induction was performed based low dose method. Orally propranolol(20 mg) was administered every 8 hours during the induction

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mustafa Khomeini hospital, Ilam University of Medical Sciences

Full name of responsible person

BA of Midwifery

Street address

Mustafa Khomeini hospital, Ilam, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Ilam University of Medical Sciences

Full name of responsible person

Dr Afra Khosravi research manager of research, Ilam University of Medical Sciences

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Ilam 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**

Department of Midwifery, Ilam University of Medical Sciences

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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