Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of oxytocin alone versus oxytocin plus intravenous and oral propranolol on labor progression

Protocol summary

Summary

The aim of this study is to compare the effects of oxytocin alone and oxytocin in combination with intravenous and oral propranolol on labor progression. This study will be done as a randomized clinical trial study in Sanandaj Besat Hospital. Total of 123 pregnant women who had inclusion criteria divided into three groups using triplex random blocks. The sample size in each group is 41 cases. Inclusion criteria included: 38 to 41 weeks gestational age, nuliparity, singleton, cephalic presentation, fetal heart rate 120 to 160 beats per minute, approximate weight of 2,500 to 4,000 gr (confirmed by examination or ultrasound), the maternal heart rate between 60 to 130 beats per minute, intact membranes and bishop score equal to or less than 5 . Exclusion criteria included: CPD, any history of previous surgery on the uterus, fetal distress, the risk of macrosomia or polyhydramnius, SBP≤100, PR≤60, PR≥130 min, any history of cardiopulmonary disease, metabolic disease of mother or taking medicine for any illness by mother. In the oxytocin alone group, use of oxytocin will start at 2mIU/min and every 15 minutes the same amount will added to create a good contraction (3 contractions in 10 minutes) this continues maximally up to 8 hours and 30 mIU. In entering the active phase of labor induction continues to delivery, in case of no entry to the active phase (3- 4 cm Dilation) stop induction after 8 hours and continues it the next day. In the absence of response to induction the second day will be cesarean section. In the oxytocin with intravenous propranolol group, concurrent with the induction 2 mg propranolol will infuse intravenously and slowly and two hours after administration, patient will be examined vaginally. If after two hours cervical dilation did not change propranolol dose repeated just for another time and induction continues. Patient will be controlled and decision will be made to continue induction to delivery or termination of pregnancy with cesarean section. Patient`s blood pressure every hour and fetal heart rate every 15 minutes will be controlled. In the oxytocin with oral propranolol group, from beginning of induction 20 mg propranolol administered orally, If after four hours cervical dilation did not change propranolol dose repeated just for another time and induction continues. Patient will be controlled and decision will be made to continue induction to delivery or termination of pregnancy with cesarean section.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016103012789N13**
Registration date: **2016-12-04, 1395/09/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-04, 1395/09/14

Registrant information

Name
Masoud Rasolabady
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Kurdistan University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of oxytocin alone versus oxytocin plus intravenous and oral propranolol on labor progression

Public title

Comparing the effect of oxytocin alone versus oxytocin plus intravenous and oral propranolol on labor progression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Nulliparity, singleton, cephalic presentation, fetal heart rate between 120 to 160 beats per minute, approximate weight of 2,500 to 4,000 (by examination or ultrasound), the maternal heart rate between 60 to 130 beats per minutes. Exclusion Criteria: CPD, any history of previous surgery on the uterus, fetal distress, the risk of macrosomia or polyhydramnius, SBP≤100, PR≤60, PR≥130 min, any history of cardiopulmonary disease, metabolic disease of mother or taking medicine for any illness by mother.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **123**

Randomization (investigator's opinion)

Randomized

Randomization description

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 og Kurdistan University of Medical Sciences

Street address

Pasdaran St.,Kurdistan University of Medical Sciences, Sanandaj, Iran

City

Sanandaj

Postal code

Approval date

2016-02-20, 1394/12/01

Ethics committee reference number

IR.MUK.REC.1394.403

Health conditions studied

1

Description of health condition studied

Induction and Promotion of labor

ICD-10 code

O80.0

ICD-10 code description

Spontaneous vertex deliveryr

Primary outcomes

1

Description

The duration of phases of labor

Timepoint

From the intervention to delivery

Method of measurement

vaginal exam

Secondary outcomes

1

Description

pregnancy ending in caesarean section

Timepoint

After the second period of injection

Method of measurement

Based on the indications for cesarean section

Intervention groups

1

Description

Intervention group oxytocin alone with dose 2 mIU/min which increase every 15 min

Category

Treatment - Drugs

2

Description
Intervention group oxytocin plus intravenous propranolol, oxytocin with dose 2 mIU/min which increase every 15 min and propranolol 2 mg/ml IV
Category
Treatment - Drugs

3

Description
Intervention group oxytocin plus oral propranolol, oxytocin with dose 2 mIU/min which increase every 15 min and propranolol 20 mg oraly
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Dr. Narjes Marjani
Street address
Besat Hospital, Keshavarz St., Mardokh Cross Road, Sanandaj, Iran
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Kurdistan University of Medical Sciences
Full name of responsible person
Dr. Ebrahim Ghaderi
Street address
Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran
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Sanandaj
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 of Kurdistan 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
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Person responsible for scientific inquiries

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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