

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparing effect of oxytocin versus oxytocin-propranolol combination on labor progression

Protocol summary

Summary

Objectives: The Main objective of this study is to compare the effect of oxytocin versus oxytocin-propranolol on labor progression. **Study design:** This study will be done randomized single - blind clinical in Sayyad Shirazi Hospital, Gorgan. **Inclusion/exclusion criteria:** Inclusion criteria includes 37 to 41 weeks gestational age according to certain LMP and confirmed ultrasound in the first quarter, also nulliparity, singleton, cephalic presentation, intact membranes and bishop score equal to or less than 5 are among the inclusion criteria. Exclusion criteria includes CPD, any history of previous surgery on the uterus, fetal distress, the risk of macrosomia or polyhydramnios, $SBP \leq 100$, $PR \leq 60$, $PR \geq 120$ min, any history of cardiopulmonary disease, metabolic disease of mother or taking medicine for any illness by mother. **Interventions:** In oxytocin 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. 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 propranolol group before induction, 2 mg propranolol will infuse intravenously and slowly and then induction starts with oxytocin the same as mentioned above. If the condition continues for the second day, use injection of 2 mg propranolol through vein and continue all induction processes. Control patient's blood pressure and fetal heart rate in every 15 minutes and follow the patient status and note down the information until delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092629983N1**

Registration date: **2016-11-15, 1395/08/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-15, 1395/08/25

Registrant information

Name

Elaheh Amiri

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 17 3225 1391

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Recruitment status

Recruitment complete

Funding source

Gorgan Congenital Malformations Research Center of Golestan University of Medical Sciences, Gorgan, Iran.

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-04-20, 1396/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of oxytocin versus oxytocin-propranolol combination on labor progression

Public title

Comparing effect of oxytocin versus oxytocin-propranolol combination on labor progression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 37 to 41 weeks gestational age based on reliable LMP and ultrasound confirmation in the first quarter, also nulliparity; singleton, cephalic presentation; intact membranes, bishop score equal to or less than 5. Exclusion criteria: CPD; any history of previous surgery on the uterus; fetal distress; the risk of macrosomia or polyhydramnios; SBP $\leq$ 100; PR $\leq$ 60; PR $\geq$ 120 min; any history of cardiopulmonary disease; known metabolic disease of mother or taking medicine for any illness in the mother.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 130

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 of Golestan University of Medical Sciences

Street address

Medical Faculty, Golestan University of Medical Sciences, Hirakan avenue, Gorgan, Iran

City

Gorgan

Postal code

4917867439

Approval date

2016-10-02, 1395/07/11

Ethics committee reference number

IR.Goums.REC.1395.144

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 delivery

Primary outcomes

1

Description

The duration of phases of labor

Timepoint

Since the intervention until delivery

Method of measurement

vaginal exam

Secondary outcomes

1

Description

Neonate's Apgar

Timepoint

After Delivery

Method of measurement

According to the protocol

2

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 with dose 2 mIU/min which increase every 15 min

Category

Treatment - Drugs

2

Description

Intervention group oxytocin- propranolol, oxytocin with dose 2 mIU/min which increase every 15 min and propranolol 2 mg/ml IV

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi Hospital

Full name of responsible person

Dr. Sepideh Bakhshandeh Nosrat

Street address

Sayyad Shirazi Hospital, Sayyad Shirazi Blvd

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan Congenital malformations research center,
Golestan University of Medical Sciences, Gorgan, Ira

Full name of responsible person

Dr. Elham Mobasheri

Street address

Gorgan Congenital malformations research center,
Sayyad Shirazi hospital, Golestan University of
Medical Sciences

City

Gorgan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gorgan Congenital malformations research center,
Golestan University of Medical Sciences, Gorgan, Ira

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

Golestan University of Medical Sciences

Full name of responsible person

Dr. Elaheh Amiri

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Sayyad Shirazi Hospital, Golestan university of
medical sciences

Full name of responsible person

Dr. Elaheh Amiri

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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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