Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Randomized clinical trial of the efficacy of oxytocin with propranol and oxytocin with placebo on the labor augmentation.

Protocol summary

Summary

This study will be conducted to compare the effect of oxytocin with and without propranolol in labor augmentation subjects. All pregnant women over 37 weeks gestational age, single fetus in cephalic and heart rate 120-160/ min and about 2500-3500 g fetal weight who are in active phase of labor and are suffering from failure to progress, after their informed consent will be recruited . The participants will be randomly divided into two groups. The first group will recieve oxytocin with propranolol and the second group, oxytocin and placebo. Study outcomes are: the time interval between the start of augmentation and delivery, the average dosage of oxytocin, the length of first and second stages of labor, cesarean section rates and its indications (failure to progress or fetal distress), maternal complications including uterine atony (failure to follow proper contraction of the uterus in labor), complications during labor including hyper stimulation ,fetal distress, meconium and placental abruption (placenta abruption from their fetus before birth) and neonatal outcomes including Apgar score 1 and 5 minutes of birth, admition in NICU and birth weight in two groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902141096N2**
Registration date: **2011-05-05, 1390/02/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-05-05, 1390/02/15

Registrant information

Name

Seyede Hajar Sharami

Name of organization / entity

Guilan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

sharami@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Guilan university of medical sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial of the efficacy of oxytocin with propranol and oxytocin with placebo on the labor augmentation.

Public title

Efficacy of oxytocin with placebo and oxytocin with propranol on the labor augmentation.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: Primiparous pregnant women with single fetus and cephalic presentation the top 37 weeks of pregnancy (According to reliable LMP or

ultrasound the first trimester) with intact membrance And fetal heart rate between 120 to 160 beats per minute and estimated fetal weight by ultrasound examination or visitors between 2500 and 4000 g and in the active phase of labor had no failure to progress. Exclusion criteria: Multi-parity, History of surgery on the uterus, malpresentation (non-cephalic), Mismatch over maternal fetal pelvis , Fetal distress, including late deceleration (Gradually reducing the minimum and maximum heart rate after completing the contract with the minimum loss rate of 15 and may take over 15 seconds) or prolong deceleration (longs over two minutes and less than 10 minutes) , Suspected macrosomia (Estimated weight over 4000 g) ,polyhydroamnius , IUGR (Estimated fetal weight using ultrasound is lower than the tenth percentile) , Women whit systolic blood pressure 90 mmHg or less And with heart rate <60 beats per minute and Women with a history of these diseases are also excluded: HTN ,Cardiac disease (Cardiac block,CHF , Right ventricular failure secondary to pulmonary hyper tension , Sinus bradycardia, Cardiogenic shock ,Significant aortic or mitral valve disease. And lung disease (Bronchial asthma or bronchospasm, severe chronic obstructive pulmonary disease, allergic rhinitis) Patients with kidney or liver dysfunction, diabetes, patients prone to hypoglycemia, myasthenia Gravis and Wolf - Parkinson – White.

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **118**

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
Vice Chancellor for research, Guilan University of Medical Science

Street address
Mellat St., Namjoo Ave

City
Rasht

Postal code

Approval date
2010-03-15, 1388/12/24

Ethics committee reference number
802

Health conditions studied

1

Description of health condition studied
Single spontaneous delivery

ICD-10 code
O80.0

ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
The effect of oxytocin with propranolol on augmentation

Timepoint
Every hour

Method of measurement
After entering an active phase of labor the patient is examined vaginally.

2

Description
The effect of oxytocin without propranolol on augmentation

Timepoint
Every hour

Method of measurement
After entering an active phase of labor the patient is examined vaginally.

3

Description
The effect of propranolol with and without oxytocin on augmentation

Timepoint
Every hour

Method of measurement
After entering an active phase of labor the patient is examined vaginally.

Secondary outcomes

1

Description
The frequency of cesarean section in pregnant women suffering from failure to progress in study groups

Timepoint

Active Phase of labor and then each hour

Method of measurement

vaginal examination for delitation and effacement

2

Description

The frequency of Apgar scores below 7 in study groups

Timepoint

First and fifth minutes of birth

Method of measurement

Sum of all five Apgar score: heart rate, respiratory effort, muscle tone, irritability, and color

3

Description

The average duration of first stage of laborinduced with oxytocin and placebo group

Timepoint

Active Phase of labor and then each hour to full dilatation

Method of measurement

Vaginal examination

4

Description

The average duration of first stage of labor in study groups

Timepoint

Active Phase of labor and then each hour to full dilatation

Method of measurement

Vaginal examination

5

Description

The average duration of second stage of labor in study groups

Timepoint

Every 15 minutes from full dilatation to delivery

Method of measurement

Vaginal examination

6

Description

The uterine inertia in study groups

Timepoint

after delivery every 15 minutes in the first hour, every hour in 4 hours and every 4 hours in 24 hours of labor

Method of measurement

Physical examination for uterus contractions and vagina bleeding

7

Description

The prevalence of meconium in study groups

Timepoint

Active phase of labor after amniotomy and then hourly

Method of measurement

Amniotomy and vaginal examination

8

Description

Prevalence of placental abruption in the study group

Timepoint

Active phase of labor and then hourly

Method of measurement

checking bleeding and contractions

9

Description

The prevalence of fetal distress in study groups

Timepoint

Every 15 minutes

Method of measurement

Listening to the fetal heart rate by Sonic aid

10

Description

The dosage of oxytocin in study groups

Timepoint

In the active phase of labor and then every hour until reaching 3 45-60 sec contractions in 10 min

Method of measurement

Checking contractions with tochometric device

Intervention groups

1

Description

In Primiparous pregnant women suffering from failure to progress in the active phase of labor, 10 units of Oxytocin in one liter of Ringer lactate with 2 mg of propranolol is injected intravenously

Category

Treatment - Drugs

2

Description

In Primiparous pregnant women suffering from failure to progress in the active phase of labor, 10 units of Oxytocin in one liter of Ringer lactate with 2 mg of distilled water as a placebo is injected intravenously

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital,Rasht

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research-Guilan University of Medical Sciences
Full name of responsible person
Dr. Abdolrasol Sobhani
Street address
Mellat St., Namjoo Ave
City
Rasht
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-Guilan 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
Guilan University of Medical Sciences
Full name of responsible person
Dr. Seyede Hajar Sharami
Position
Associate professor of Guilan University of Medical Sciences
Other areas of specialty/work
Street address
Reproduction Health research center-Alzahra hospital-Namjo street
City
Rasht
Postal code
Phone
+98 13 1322 5624
Fax
Email
sharami@gums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Dr. Seyede Hajar Sharami
Position
Associate professor of Guilan University of Medical Sciences
Other areas of specialty/work
Street address
Reproduction Health research center-Alzahra hospital-Namjo street
City
Rasht
Postal code
Phone
+98 13 1322 5624
Fax
Email
sharami@gums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Reproductive Health Research Center
Full name of responsible person
Seyede Fatemeh Dalil Heirati
Position
Bs in Midwifery
Other areas of specialty/work
Street address
Reproduction Health research center-Alzahra hospital-Namjoo street
City
Rasht
Postal code
Phone
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