

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Assessment the effect of intraumbilical vein Oxytocin injection in comparison to normal saline on third stage of labor

Protocol summary

Summary

This study is aimed to compare the effect of intraumbilical vein oxytocin and normal saline on the third stage of labor. Pregnant women are randomly allocated into two groups of oxytocin and normal saline. In overall, 75 patients are participated in the study. It is a double-blind study (obstetricians and patients). Inclusion criteria: cephalic presentation and patients with first pregnancy. Exclusion criteria: multi gravity; severe anemia; uterine scar. In both groups, umbilical cord at a distance of one centimeter from the introitus is clamped immediately after the expulsion of the fetus. In the first group, 20 ml of normal saline is injected into the umbilical vein using syringe, and to prevent leakage of injected fluid, cord is re-clamped from above the space of injection site. In the second group, according to the same protocol, 30 units of oxytocin solved in 17 ml of normal saline (total 20 ml), is injected by needle into the umbilical vein. Time between intravenous injection of umbilical cord and placenta is measured by using of stopwatch. In the present study, hemoglobin and hematocrit level are also measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052810340N15**

Registration date: **2017-06-29, 1396/04/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-29, 1396/04/08

Registrant information

Name

Mohammad Aryaie

Name of organization / entity

Golestan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Science

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of intraumbilical vein Oxytocin injection in comparison to normal saline on third stage of labor

Public title

The effect of Oxytocin on the duration of third stage of labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: First pregnancy; singleton pregnancy; gestational age term (over 37 weeks); signs of labor (regular contractions with the appropriate power 3 per 10 minutes); cephalic presentation. Exclusion criteria were considered as: Multi gravity; polyhydramnios; severe

anemia; uterine scar; the use of forceps or vacuum; placenta previa; prolonged labor (over 20 hours); bleeding before delivery.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Patients would be allocated in to 2 groups using block allocation (block size 6) method.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Golestan University of Medical Science

Street address

4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan

City

Gorgan

Postal code**Approval date**

2017-05-16, 1396/02/26

Ethics committee reference number

IR.GOUMS.REC.1396.24

Health conditions studied**1****Description of health condition studied**

duration of labor

ICD-10 code

O00-O99

ICD-10 code description

Pregnancy, childbirth and the puerperium

Primary outcomes**1****Description**

Duration of third stage of labor

Timepoint

After intervention

Method of measurement

Stopwatch

Secondary outcomes**1****Description**

Hemoglobin

Timepoint

After intervention

Method of measurement

Blood sample

2**Description**

Hematocrit

Timepoint

After intervention

Method of measurement

Blood sample

Intervention groups**1****Description**

Control group will receive 20ml of normal saline by injection into the intraumbilical vein.

Category

Placebo

2**Description**

Intervention group will receive 30 units of oxytocin, dissolved in 17 ml of normal saline, by injection into the intraumbilical vein

Category

Treatment - Drugs

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

Shahid Sayyad Shirazi Hospital

Full name of responsible person

Ghazaleh Sadeghian

Street address

Shahid Sayyad Shirazi Hospital, Shahid Sayyad Shirazi Street, Gorgan City, Golestan Province

City
Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Mohsen Saeedi

Street address

4 Kilometer of Gorgansari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan

City

Gorgan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Golestan 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

Golestan University of Medical Science

Full name of responsible person

Ghazale Sadeghian

Position

Obstetricians

Other areas of specialty/work

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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