

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of nipple stimulation(using pump) and oxytocin infusion on the length and the bleeding of third stage of labour, bleeding and postpartum Anemia.

Protocol summary

Summary

This study will be conducted to examine the impact of nipple stimulation by pump with oxytocin infusion on the duration and the amount of the third stage bleeding and postpartum anemia. This randomized clinical trial study will be performed on 108 women aged between 18 to 35 years who would refer to Sina hospital in order to natural delivery with the amount of hemoglobin above 11, the first and second pregnancy, singleton pregnancy, gestational age between 37 to 42 weeks, without the history of cesarean delivery and postpartum bleeding. They are put randomly 54 patients in the control group and 54 people in the intervention group by simple random method. Hematocrit and hemoglobin would be measured at the time of acceptance in the both groups of intervention and control. In the intervention group, it will be done the nipple stimulation by the special pump for 5 minutes alternately for each breast and a total of 10 minutes for breasts immediately after birth and cutting the umbilical cord. In the control group, a routine care will take place immediately after delivery by infusion of 20 units of oxytocin in 1000 ml serum. It will be measured the duration and the amount of bleeding in the third stage of labor, postpartum hemorrhage, Hematocrit and Hemoglobin just 24 hours after delivery in both groups of intervention and control.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050722146N1**

Registration date: **2015-11-04, 1394/08/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-04, 1394/08/13

Registrant information

Name

Elham Dashtinezhad

Name of organization / entity

Jundishapur university of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 1336 7543

Email address

dashtinejad.e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of nipple stimulation(using pump) and oxytocin infusion on the length and the bleeding of third stage of labour, bleeding and postpartum Anemia.

Public title

The effect of nipple stimulation on bleeding of third stage of labor and postpartum Anemia.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria to the research : The age between 18 and 35 years; Singleton pregnancy; Gestational age between 37 to 42 weeks; Normal blood pressure; First and second delivery;The amount of hemoglobin before labor to be more than 11 g per dL; BMI to be between 20 to 30 kilograms per square meter; Weight of the baby to be between 2500 to 4000 gr; Normal vaginal delivery.

Exclusion criteria from the research: Women with placental abruption and placenta previa pregnancy; Women who have abnormal labor progress; Women who have had uterine surgery and cesarean; Women with a history of internal and underlying medical conditions; Women who need oxytocin for augmentation of labor; Women who have had postpartum hemorrhage in previous pregnancy; If the pregnancy to be along with oligo or poly hydramnios; If there has been fetal distress; In case of severe postpartum hemorrhage that requires more interventions; Women who had abortions.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sampling is being done through by simple random method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz,Jundishapour University of Medical Sciences

Street address

Ahvaz, Golestan Highway,Ahvaz Jundishapour University of Medical Sciences

City

Ahvaz

Postal code

6135715794

Approval date

2015-05-23, 1394/03/02

Ethics committee reference number

IR.AJUMS.REC.1394.86

Health conditions studied

1

Description of health condition studied

Bleeding in postpartum period.

ICD-10 code

O72.0

ICD-10 code description

Haemorrhage after delivery of fetus or infant

Primary outcomes

1

Description

Bleeding postpartum

Timepoint

After delivery, till 24 hours after delivery

Method of measurement

Higham chart

2

Description

postpartum Anemia

Timepoint

At the time of admission and 24 hours after delivery

Method of measurement

Hb; Hct Test

3

Description

Length of third stage of labour

Timepoint

Third stage of labour

Method of measurement

Minute

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

In the intervention group :Nipple stimulation/ 10 minutes for each nipples via pump/ after delivery.

Category

Other

2

Description

In the control group:Oxytocin infusion/20 units in 1000 milliliter at 10 cc per minute/ after delivery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Elham dashtinezhad

Street address

Kut Abdullah Road, Not far from the Alley station,Sina Hospital, Ahvaz, Iran

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for reserch of ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Elham Dashtinezhad

Street address

Ahvaz Jundishapour University of Medical Sciences,Opposite the central building, Vice Chancellor for Research, Ahvaz

City

Ahvaz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for reserch of ahvaz Jundishapour 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

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Elham Dashtinezhad

Position

Master of Midwifery

Other areas of specialty/work

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Person responsible for updating data

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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