

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of nipple stimulation and infusion of syntocinon on the induction of labour in nulliparous women and its outcomes

Protocol summary

2014-01-03, 1392/10/13

Summary

The objective of this study is to compare the effect of nipple stimulation as a natural method with syntocinon drug on the induction of labour and its outcomes. Design: This study performed on 140 nulliparous women in Hazrat Zeinab Hospital of Babbolsar. After explaining aims and method of research and getting written informed consent, samples divided by table random number to nipple stimulation group and infusion syntocinon group (70 cases in each groups). Major eligibility criteria: Study performed on nulliparous women with 18-35 years, gestational age between 38-42 weeks and having Indications for induction of labour. In case of incidence of obstetric emergencies and rupture of membrane before 4-5 cm dilatation samples excluded from the study. Interventions: In nipple stimulation group, stimulation of unilateral breast by patient performed for 15 minutes stimulation, then 15 minutes rest for 6 hours period. If there was no change in bishop score and lack of effective contraction during this period, it was considered induction failure. In syntocinon group, infusion started with 2.5mu/min and added 2.5mu/min every 15 minutes up to 40mu/min (6 hours). If there was no change in Bishop score or lack of effective contraction it was considered induction failure. Main outcome variable of this study is induction of labour.

Registrant information

Name

Shahnaz Torkzahrani

Name of organization / entity

"Shahid beheshty university of medical sciences"

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Nursing & Midwifery Faculty of Shahid Beheshty University of Medical Sciences

Expected recruitment start date

2013-10-20, 1392/07/28

Expected recruitment end date

2013-12-19, 1392/09/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of nipple stimulation and infusion of syntocinon on the induction of labour in nulliparous women and its outcomes

Public title

Comparison of the effect of nipple stimulation with syntocinon drug on the induction of labour

Purpose

Diagnostic

Inclusion/Exclusion criteria

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112515544N1**

Registration date: **2014-01-03, 1392/10/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Inclusion criteria: age of 18-35 years old, gestational age of 38-42 weeks based on LMP or ultrasound before 26 weeks: requiring termination of pregnancy for fetal or maternal indications: nulliparous woman: single fetus with cephalic presentation: intact membrane: bishop score < 4: body mass index between 20 to 30: estimated fetal weight between (4500-2500 gr): lack of any kind of diseases and high risk pregnancy: not use of any kind of chemical drug or herb to start labour for 48 hours before admission: lack of any problems (eg, tumor) in the breast. Exclusion criteria: Incidence of each type of obstetric emergencies (such as cord prolapse): discontinuing of the study by patient request :spontaneous rupture of membrane before 4-5cm dilatation.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **140**

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

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

"Ethics committee of Shahid Beheshti University of Medical Sciences"

Street address

Shahid Aarabi street, Yaman street, Shahid Chamran highway, Tehran

City

Tehran

Postal code

-

Approval date

2013-10-20, 1392/07/28

Ethics committee reference number

1392-1-86-11432

Health conditions studied

1

Description of health condition studied

labour induction

ICD-10 code

O61

ICD-10 code description

Failed induction of labour

Primary outcomes

1

Description

Bishop score

Timepoint

every 2 hours during first stage of labour

Method of measurement

by vaginal examination

Secondary outcomes

1

Description

Abnormal fetal heart rate

Timepoint

During the study

Method of measurement

Fetal monitoring device

2

Description

Apgar score

Timepoint

1&5 minute after delivery

Method of measurement

Apgar scoring System

3

Description

Pain intensity

Timepoint

During the study

Method of measurement

McGill ruler

4

Description

Length of the first and second stages of labor

Timepoint

End of delivery

Method of measurement

minute

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

nipple stimulation (intervention group). In this group unilateral breast stimulation perform for 15 minutes and then 15 minutes rest to 6 hours period.

Category

Treatment - Other

2**Description**

control group (infusion of syntocinon): 10 units syntocinon add into one litter of ringer serum. Infusion start with 2.5 mu/min and add 2.5mu/min every 15 minutes up to 40 mu/min.

Category

Treatment - Drugs

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

Hazrat Zeinab Hospital

Full name of responsible person

Negar Hariri

Street address

Shahid Chamran Street, Babolsar

City

Babolsar

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research,Nursing & Midwifery Faculty of Shahid Beheshty University of Medical Sc

Full name of responsible person

Dr.Masume Simbar

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Intersection of Valiasr-Nyayesh street,Tehran

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Tehran

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,Nursing & Midwifery Faculty of Shahid Beheshty University of Medical Sc

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**

Nursing & Midwifery Faculty of Shahid Beheshty Medical Science University

Full name of responsible person

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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