Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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 for15 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 every15 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.

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

2014-01-03, 1392/10/13

Registrant information

Name
Shahnaz Torkzahrani
Name of organization / entity
"Shahid beheshty university of medical sciences"
Country
Iran (Islamic Republic of)
Phone
+98 218820512
Email address
zhranishahnaz@sbmu.ac.ir

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

Inclusion criteria: age of18-35 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 wemon؛ single fetous 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
every2 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
Fetel 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
Lenght 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
Street address
Intersection of Valiasr-Nyayesh street,Tehran
City
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
Negar Hariri
Position
Last semester of the Master of Midwifery
Other areas of specialty/work
Street address
Intersection of Valiasr-Nyayesh street,Tehran
City
Tehran
Postal code
4741741996
Phone
+98 11 2526 3296
Fax
Email
negarhariri@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Nursing & Midwifery Faculty of Shahid Beheshty Medical Science University
Full name of responsible person
Shahnaz Torkzahrani
Position
student of phd
Other areas of specialty/work
Street address
Intersection of Valiasr-Nyayesh street,Tehran
City
Tehrran
Postal code
198571443
Phone
+98 218865536671
Fax
-
Email
zahranishahnaz@yahoo.com

Web page address
-

Person responsible for updating data

Contact

Name of organization / entity
Nursing & Midwifery Faculty of Shahid Beheshty Medical Science University

Full name of responsible person
Negar Hariri

Position
Last semester of the Master of Midwifery

Other areas of specialty/work

Street address
Intersection of Valiasr-Nyayesh street, Tehran, Iran

City
Tehran

Postal code
4741741996

Phone
+98 11 2526 3296

Fax
-

Email
negarhariri@yahoo.com

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