

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Transcervical Catheter and Laminaria efficacy on induction of labor in post term pregnancy

Protocol summary

Summary

This randomized not blinded clinical trial study performs on 100 pregnant patients. Inclusion criteria: Pregnant women with post term pregnancy are candidate for induction of labor, bishop score < 5 , and vertex presentation of fetus. Exclusion criteria: Spontaneous contraction, rupture of membranes and have a uterine scar, bishop score > 5 , placenta previa and any contraindication of vaginal delivery. The main purpose of this study is comparing Laminaria and Transcervical catheter efficacy for induction of labor. Patients divide to two groups with 50 person in each of them. For group 1 insert Transcervical catheter and for the other one use Laminaria for ripening of cervix. 30 minute after inserting, induction of labor by oxytocin was started according to classic protocol. Then, the time lapse from the beginning of induction to enter the active phase of labor and also from the start of induction till delivery and appearing the side effects in both groups will assess.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105016355N1**

Registration date: **2011-09-07, 1390/06/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-07, 1390/06/16

Registrant information

Name

Leila Hormozi

Name of organization / entity

Ahwaz Jondishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Transcervical Catheter and Laminaria efficacy on induction of labor in post term pregnancy

Public title

Comparison of Transcervical Catheter and Laminaria efficacy on induction of labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with post term pregnancy are candidate for induction of labor; bishop score < 5 ; vertex presentation of fetus. Exclusion criteria: Spontaneous contraction; rupture of membranes and have a uterine scar; bishop score > 5 ; Placenta previa; any contraindication of vaginal delivery.

Age

From **15 years** old to **44 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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**

empty

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

Ahwaz Jondishapur University of Medical Sciences
Ethic committee

Street address

Golestan Bolvar,Ahvaz

City

Ahwaz

Postal code

6193673166

Approval date

2010-06-07, 1389/03/17

Ethics committee reference number

ETH-006

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

Post term pregnancy

ICD-10 code

048

ICD-10 code description

Prolonged pregnancy

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

Induction of labor to delivery interval

Timepoint

Per 2 hours

Method of measurement

Cervical dilatation by vaginal examination (cm)

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

Induction of labor to active phase interval

Timepoint

Per 2 hours

Method of measurement

Cervical dilatation by vaginal examination (cm)

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

Intervention group 1. Transcervical catheter (Foley) 16F, contains 30 cc saline, between internal os and fetus head, 30 minutes before oxytosin

Category

Treatment - Other

2**Description**

Intervention group 2. Laminaria medium size (3-4) in endocervical canal, 30 minutes before oxytosin

Category

Treatment - Other

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

Ahvaz Emam Khomeini Hospital

Full name of responsible person

Dr. Leila Hormozi - Obstetrics & Gynecology Resident

Street address

Ahvaz Emam Khomeini Hospital

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

Vice chancellor for research, Ahvaz Jundishapour
University of Medical Sciences

Full name of responsible person

Dr. Mostafa Fegghi

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Ahvaz Jondishapur University of Medical Sciences,
Golestan Bolvar

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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 research, Ahvaz Jundishapur 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 Jondishapur University of Medical Sciences

Full name of responsible person
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Position
Obstetrics & Gynecology Resident

Other areas of specialty/work

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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