

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of intramuscular administration of Dexamethasone on the induction of labor and duration of labor and its complications

Protocol summary

Summary

Induction of labor is one of the most common procedures during pregnancy. Various methods for cervical ripening and labor induction have been described, but the role of corticosteroids in the process of labor is not entirely understood. The aim of this study is to determine the effect of intramuscular dexamethasone on cervical ripening and induction of labor and its complications. This study was a double blinded, randomized clinical trial on 120 nulliparous women ≥ 38 weeks and bishop score ≥ 7 with inclusion criteria (cephalic, singlone, membrane intact...) and exclusion criteria (vaginal bleeding, vaginal leakage, IUGR) admitted to the Ayatollah Ruhani hospital. Study group receives 8 mg (2cc) intramuscular dexamethasone phosphate 6 hours before induction. Induction starts after 6 hours for control group (n=60) following 2 cc distile water injection. Expect result was initiation of active phase of labor and duration of labor that is compare in both group. Data collection accomplishes by specific forms and data analysis does by spss-18 softwar.t test and chi-square test use for analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401221760N29**

Registration date: **2014-03-13, 1392/12/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-13, 1392/12/22

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health
Research Center, Babol University of Medical
Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Expected recruitment start date

2014-03-09, 1392/12/18

Expected recruitment end date

2014-06-08, 1393/03/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intramuscular administration of Dexamethasone
on the induction of labor and duration of labor and its
complications

Public title

Effect of intramuscular administration of Dexamethasone
on the induction of labor and duration of labor and its
complications

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with a gestational age

of 38 weeks or more; Bishop score greater than or equal to 7; Singleton pregnancy, cephalic; Normal embryo sac. Exclusion criteria: Abnormal vaginal bleeding (risk of placenta previa or placental abruption); History of any systemic diseases (HTN, DM, etc); Receiving any medical treatment except for routine supplementation in pregnancy; Suspected macrosomia (ultrasound or clinical assessment by a skilled person); Excessive uterine distension (polyhydramnios evidence); presentation non-cephalic; Active phase of labor (cervical dilatation 2-3 cm4-3 with a strong contraction in width, 10); PROM; IUGR10; Fetal distress, bad hips; Any uterine abnormalities or any uterine surgery, including Cesarean delivery on admission;

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafroz Road

City

Babol

Postal code

Approval date

2014-03-08, 1392/12/17

Ethics committee reference number

3810/پ/ز

Health conditions studied

1

Description of health condition studied

induction of labor

ICD-10 code

O60

ICD-10 code description

Preterm labour and delivery

2

Description of health condition studied

duration of labor

ICD-10 code

O60

ICD-10 code description

Preterm labour and delivery

Primary outcomes

1

Description

Reducing the time between the onset of the active phase of labor induction

Timepoint

6 hours after injection of dexamethasone and induction

Method of measurement

Clinical

2

Description

Reduce the duration of the active phase of labor

Timepoint

38 weeks to 42 weeks of gestation

Method of measurement

Clinical

3

Description

Reduction stage II of labor

Timepoint

Dilatation and expulsion of fetus

Method of measurement

Clinical

Secondary outcomes

1

Description

Apgar scores after birth

Timepoint

In the first minutes after birth

Method of measurement

Clinical

2

Description

Baby Weight

Timepoint

Birth

Method of measurement

Kg

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

Intervention groups: dexamethasone sodium phosphate (2cc) (from Caspian) is injected. After 6 h induction begins. If you do not enter an active phase (3 contractions in 10 minutes with regular dilatation 3-4 cm) 6 h after induction with oxytocin infusion rate of 5/2 mm unit in minutes starts. This amount is increased to every 15 minutes.

Category

Treatment - Drugs

2**Description**

Control group: Sterile water injections (2cc)

Category

Treatment - Drugs

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

Ayatollah Rouhani Hospital Babol

Full name of responsible person

Dr. Zeinab Pahlavan

Street address

Ayatollah Rouhani Hospital Babol , Ganjafroz Avenue

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice Chancellor for Research and Technology, Babol
University of Medical Sciences**Full name of responsible person**

Dr. Ali Bijani

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Babol University of Medical Sciences, Ganjafroz Road

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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 and Technology, Babol

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**Fatemehzahra Fertility & reproductive Health
Research Center**Full name of responsible person**

Dr. Zeinab Pahlavan

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work**Street address**Educational Center of Fatemeh Zahra, Old Road Amol -
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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**Fatemehzahra Fertility & reproductive Health
Research Center**Full name of responsible person**

Seddigheh Esmaeilzadeh

Position

Gynecologist

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Person responsible for updating data

Contact

Name of organization / entity

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Research Center

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Position

M.A

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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