Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating of Dexamethasone effects in comparison with placebo on the ripening and Induction of labor in normal delivery.

Protocol summary

Summary

This clinical trial aimed to evaluate the effect of intravenous dexamethasone in cervical ripening and induction of labor. In a double-blind, randomized clinical trial, 172 women with first pregnancy and gestational age ≤ 40 weeks and Bishop Score ≤ 4 after written consent were enrolled and randomly divided into two groups. All patients with underlying diseases, diabetes, preeclampsia, breech presentation, twin pregnancy, macrosomia, induction of labor, spontaneous rupture of amniotic sac were excluded. Bishop Score of patients determined and they received Dexamethasone and distilled water as an intravenous injection every other. The interval between the labor inductions to onset of active phase were measured and recorded. Bishop score was determined again 4 hours after injection and both groups received oxytocin for induction of labor. The interval between the active phases to second stage of labor was also measured and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052613468N1**
Registration date: **2013-09-20, 1392/06/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-09-20, 1392/06/29

Registrant information

Name

Negin Mahboob Asiabar

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating of Dexamethasone effects in comparison with placebo on the ripening and Induction of labor in normal delivery.

Public title

Effects of intravenous Dexamethasone on labor induction.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: All nulliparous women with gestational age>40 weeks; Bishop score≤ 4. Exclusion criteria: Bishop score> 4; Diabetes; pre-eclampsia; maternal diseases; Bridge presentation; twin pregnancy; initiation of labor pain; Spontaneous rupture of the amniotic sac.

Age

No age limit

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **172**
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
Ethic Committee of Qazvin University of Medical Sicense
Street address
Qazvin University of Medical Sicense, Shahid Bahonar Boulvard
City
Qazvin
Postal code
Approval date
2013-03-05, 1391/12/15
Ethics committee reference number
28/20/7041

Health conditions studied

1

Description of health condition studied
Labour Induction with Dexamethasone
ICD-10 code
061.9
ICD-10 code description
Failure of Induction

Primary outcomes

1

Description
Ripening of cervix
Timepoint
In initiation of study
Method of measurement
Based on Boshop score

Secondary outcomes

1

Description
Neonetal APGAR
Timepoint
First and fifth minutes after delivery
Method of measurement
Standard method

Intervention groups

1

Description
After determining of Bishop score in case group 8 mg dexamthasone administrated by intravenous injection and 4 hours later Bishop score determined again and oxytocin administrated for labor induction.
Category
Treatment - Other

2

Description
After determining of Bishop score in control group2 cc water for injection (equal to dexamethasone volume) administrated by intravenous injection and 4 hours later Bishop score determined again and oxytocin administrated for labor induction.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Obestetric and Gynecology ward, Kowsar Hospital, Qazvin University of Medical Sciences
Full name of responsible person
Street address
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Qazvin University of Medical Science
Full name of responsible person
Mr. Reza Ghadami
Street address

Shahid Bahonar Boulevard, Vice Chancellor for Research of Qazvin University of Medical Science

City

Qazvin

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 of Qazvin University of Medical Science

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

Qazvin University of Medical Sciences

Full name of responsible person

Negin Mahboob Asiabar

Position

Gynecology Resident

Other areas of specialty/work

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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