

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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  $\leq 40$  weeks and Bishop Score  $\leq 4$  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)

##### Phone

+98 28 1333 6001

##### Email address

nmahboob@qums.ac.ir

##### 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  $\leq 4$ . Exclusion criteria: Bishop score  $> 4$ ; Diabetes; pre-eclampsia; maternal diseases; Breech 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  
Boulevard

##### 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 group 2 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**

**Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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Semnan University of Medical Science

**Full name of responsible person**

Mehrdad Zahmatkesh

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Research Expert

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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*