

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### A comparison between betamethasone and dexamethasone on biophysical profile

#### Protocol summary

##### Summary

The aim of this study is comparison of betamethasone with dexamethasone on amniotic fluid index, inclusion criteria is pregnant women with gestational age of 28wk -32wk at risk of preterm labor, exclusion criteria is gestational diabet mellitus in pregnant women or high blood sugar in pregnant women, every systemic disease in mother, every high blood pressure in mother, every vaginal leak in mother, small gestational age or intra uterine growth retardation, consumption of any drug in mother except supplementation, all case studies are pregnant women with gestational age 28wk - 32wk of 75 women. these 75 women are divided into two groups. In the first group dexamethasone is used while in the second group betamethasone is used. It is noted that before and three days after consumption of these drugs in each group, Amniotic Fluid Index (AFI) and Non Stress Test (NST) are performed and the increase or decrease of Amniotic Fluid Index (AFI) and changes in Non Stress Test (NST) are taken into consideration.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201212307513N2**  
Registration date: **2013-12-27, 1392/10/06**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-12-27, 1392/10/06

##### Registrant information

###### Name

Hatav Ghasemi Tehrani

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 913 113 4081

###### Email address

tehrani@med.mui.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Esfahan University of Medical Science

###### Expected recruitment start date

2011-06-01, 1390/03/11

###### Expected recruitment end date

2014-06-02, 1393/03/12

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

A comparison between betamethasone and dexamethasone on biophysical profile

###### Public title

A comparison between betamethasone and dexamethasone on biophysical profile in 28wk - 32wk pregnant women at risk of preterm labor

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

EXCLUSION :1:having diabet mellitus & rising blood pressure and consumption of drug except supplement and small for gestational age fetus & anomaly in fetus & premature rupture of membrane INCLUSION:1:pregnant woman 28wk-34wk with at least once preterm labor in her past medical history or at risk of preterm labor

###### Age

From **16 years** old to **44 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **75**

**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**

Etical committee of medical scienceof esfahan

**Street address**

Hezar jarib st

**City**

Esfahan

**Postal code**

20212-45678

**Approval date**

2011-03-06, 1389/12/15

**Ethics committee reference number**

389484

**Health conditions studied**

1

**Description of health condition studied**

preterm labor

**ICD-10 code**

O60.0

**ICD-10 code description**

Preterm labour without delivery

**Primary outcomes**

1

**Description**

biophysical profile

**Timepoint**

befor &after corticosteroide adminstration

**Method of measurement**

sonography

**Secondary outcomes**

1

**Description**

sonography biophysical profile and non stress test

**Timepoint**

3 days after administration of corticosteroides in each group

**Method of measurement**

sonography and non stress test

**Intervention groups**

1

**Description**

Group 1: betamethasone 12 mg per day at most 2 doses.

**Category**

Treatment - Drugs

2

**Description**

Group 2: Dexamethasone 8 mg in each 12 hours at most 4 doses.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Alzahra Hosital

**Full name of responsible person**

Hatav GHasemi Tehrani

**Street address**

Alzahra hospital

**City**

Isfahan

2

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti Hospital

**Full name of responsible person**

zahra komrani

**Street address**

Esfahan, beheshti hospital

**City**

Esfahan

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Science

**Full name of responsible person**

Hatav GHasemi Tehrani

**Street address**

Alzahra Hospital

**City**

Isfahan

**Grant name**

-

**Grant code / Reference number**

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**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

beheshti hospital

**Full name of responsible person**

zahra komrani

**Position**

obstetric resident

**Other areas of specialty/work****Street address**

Beheshti hospital, Felezi bridge, Esfahan, Iran.

**City**

esfahan

**Postal code**

81848-51153

**Phone**

+98 31 1236 7001

**Fax****Email**

zkomran@gmail.com

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

beheshti hospital

**Full name of responsible person**

dr ghasemi tehrani

**Position**

specialist in obstetric and gynecology

**Other areas of specialty/work****Street address**

Beheshti hospital, Felezi bridge, Esfahan, Iran.

**City**

esfahan

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tehrani@med.mui.ac.ir

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### Person responsible for updating data

**Contact****Name of organization / entity**

beheshti hospital

**Full name of responsible person**

zahra komrani

**Position**

obstetric and gynecology resident

**Other areas of specialty/work****Street address**

isfahan

**City**

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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*