

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.

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

specialist in obstetric and gynecology

Other areas of specialty/work

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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