Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison between betamethasone and dexamethasone on biophysical profile

Protocol summary

Summary

The aim of this study is comparison of betamethasone with dexametasone 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
biophisical 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
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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
--
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
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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