

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of antenatal prophylactic betamethasone injection on neonatal respiratory distress syndrome reduction in multifetal pregnancies

Protocol summary

Study aim

Effect of antenatal prophylactic betamethasone injection on neonatal respiratory distress syndrome reduction in multifetal pregnancies

Design

The clinical trial included a control group without betamethasone and one intervention group receiving betamethasone 12 mg muscular, study is one-blinded. Groups are parallel. Patients will be randomly assigned to two intervention and control groups using a random number table based on the case number.

Settings and conduct

This study will be done about effect of antenatal prophylactic betamethasone injection on neonatal respiratory distress syndrome reduction in multifetal pregnancies. All mothers encoded in both groups will be included in the study and evaluated, and the person evaluating the occurrence of respiratory syndrome will be unaware of how to group and receive the betamethasone of the mother, and the study will be done blinded.

Participants/Inclusion and exclusion criteria

Entrance criteria: Mothers with multiple pregnancies under 28 weeks
Non-compliance criteria: A mother's disease that restricts the administration of corticosteroids.

Intervention groups

Intervention group 1: Betamethasone ampoule (manufactured in Iran), 12 mg Muscular, 24 hours apart, will be injected into two doses between the weeks of gestation 28-26. Control group: Group without betamethasone

Main outcome variables

Neonatal respiratory distress syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180227038879N1**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Fatemeh Abbasalizadehf

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3553 9161

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-05, 1396/11/16

Expected recruitment end date

2019-09-07, 1398/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of antenatal prophylactic betamethasone injection on neonatal respiratory distress syndrome reduction in multifetal pregnancies

Public title

Effect of antenatal prophylactic betamethasone injection on neonatal respiratory distress syndrome reduction in multifetal pregnancies

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Multiple pregnancy less than 28 weeks

Exclusion criteria:

Dissatisfaction patient to participate in this study.
Motherhood disease that limits the administration of corticosteroids. Multifetal pregnancies that has another risk factor for early childbirth.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with using a random number table based on the case number, will be randomly assigned into two intervention and control groups

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2018-02-13, 1396/11/24

Ethics committee reference number

IR.TBZMED.REC.1396.1000

Health conditions studied**1****Description of health condition studied**

حاملگی چند قلوئی

ICD-10 code

Z35.4

ICD-10 code description

Supervision of multiparity pregnancy

Primary outcomes**1****Description**

Neonatal respiratory distress syndrome

Timepoint

Immediately after birth

Method of measurement

Newborn clinical examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Betamethasone ampoule (manufactured in Iran), 12 mg(Intramuscular injection) per 24 hours, will be injected into two doses between the weeks of gestation 28-26.

Category

Treatment - Drugs

2**Description**

Control group: Group without receive betamethasone

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Fatemeh Abbasalizadeh

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Alzahra Hospital, South Artesh St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research,Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Alireza Rashidi
Street address
خیابان گلگشت- ساختمان مرکزی شماره دو-طبقه سوم
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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,Tabriz University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Fatemeh Abbasalizadeh
Position
Professor of Obstetrics and Gynecology
Latest degree
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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available