

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Efficacy of Azithromycin in prevention of bronchopulmonary dysplasia in premature newborn infants

Protocol summary

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Summary

We will conduct a study in preterm newborn infants admitted in NICU to determine efficacy of Azithromycin in prevention of BPD. Premature newborn infant born in Al-Zahra hospital in Tabriz will be randomly assigned into the two following groups. The intervention group will receive oral Azithromycin 10mg/kg from 7th day for one week and then 5 mg/kg for another week and the control group do not receive any intervention. All newborn infants will be treated according to hospital guidelines for respiratory distress syndrome. The patients will be followed for 3 months and Fio₂, O₂ saturation (spo₂), duration of oxygen therapy and hospitalization will be determined and compared between groups.

Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor of Tabriz University of Medical Sciences(Pediatric Health Research Center)

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902223915N1**

Registration date: **2011-01-03, 1389/10/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-01-03, 1389/10/13

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1526 2253

Email address

Scientific title

Efficacy of Azithromycin in prevention of bronchopulmonary dysplasia in premature newborn infants

Public title

Azithromycin and prevention of bronchopulmonary dysplasia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: birth weight less than 1500g, feeding starting before 7 days, parental consent for study

Exclusion criteria: major congenital anomalies, congenital heart disease, chromosomal defects, death before 7th day of birth, sign of necrotising enterocolitis before 7th day of birth, severe intraventricular hemorrhage (grade 3 or 4)

Age

From **7 years** old to **120 years** old

Gender

Both

Phase

0

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tabriz University of Medical Sciences

Street addressVice Chancellor of Research, Third floor, Building
No.2, Tabriz University of Medical Sciences, Golgasht
street**City**

Tabriz

Postal code**Approval date**

2010-07-26, 1389/05/04

Ethics committee reference number

4931/4/5

Health conditions studied**1****Description of health condition studied**bronchopulmonary dysplasia, need for oxygen beyond 28
days of birth**ICD-10 code**

P27.1

ICD-10 code descriptionbronchopulmonary dysplasia originating in perinatal
period**Primary outcomes****1****Description**

duration of need for oxygen

Timepoint

daily

Method of measurement

days count before O2 discontinue

2**Description**

needed FIO2

Timepoint

daily

Method of measurement

oxymeter and blender

3**Description**

spo2

Timepoint

daily

Method of measurement

pulseoxymetry

Secondary outcomes**1****Description**

duration of hospitalization

Timepoint

days of hospital stay

Method of measurement

time between admission and discharge

Intervention groups**1****Description**Azithromycin, orally, from 7th day of birth for one week
with a single dose of 10 mg/kg/daily and then 5
mg/kg/daily for subsequent week**Category**

Treatment - Drugs

2**Description**

Control group: no intervention

Category

N/A

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

NICU. Al Zahra Hospital

Full name of responsible person

Dr Gharehbaghi

Street address

South Artesh Street

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences,

Full name of responsible person

Dr Mohamad Barzegar

Street address

Pediatric Health Research Center, Children Hospital, Sheshgelan Street

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pediatric Health Research Center, Tabriz University of Medical Sciences,

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Manizheh Mostafa Gharehbaghi/ Dr Majid Mahaleii

Position

Associate Professor/ Fellowship of Neonatology

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Manizheh Mostafa Gharehbaghi

Position

Associate Professor of Pediatrics and neonatology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Manizheh Mostafa Gharehbaghi

Position

Associate Professor of Pediatrics

Other areas of specialty/work

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Web page address

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