

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparative study of the effect of dexamethasone and injectable hydrocortisone in reducing the need for oxygen in preterm infants with high risk of bronchopulmonary dysplasia admitted to the NICU of Ayatollah Mousavi Hospital in Zanjan in 2021-22.

Protocol summary

Study aim

Comparative study of the effect of dexamethasone and injectable hydrocortisone in reducing the need for oxygen in preterm infants with high risk of bronchopulmonary dysplasia

Design

A randomized, double blinded, clinical trial with a parallel group design of 60 infants. Randomisation was carried out by Rand function of Microsoft Excel software.

Settings and conduct

In this clinical trial study, 60 eligible neonates admitted to the neonatal intensive care unit of Ayatollah Mousavi Hospital in Zanjan are randomly assigned into two groups of 30 and are evaluated one week after receiving dexamethasone or hydrocortisone and from the day 28.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Fetal age less than 33 weeks. The risk of bronchopulmonary dysplasia more than 60% according to the NICHD definition. Exclusion criteria: Active systemic or pulmonary infection. Existence of congenital anomalies and metabolic diseases requiring surgery.

Intervention groups

Infants of the dexamethasone group will receive Dexamethasone injection from day 14 of birth (0.2 mg per kg body weight for the first 3 days and 0.1 mg per kg body weight for the next 4 days) and infants of the hydrocortisone group will receive hydrocortisone injection from the 14th day of birth (1 mg per kg of body weight for 7 days).

Main outcome variables

Oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201222049802N3**

Registration date: **2022-01-25, 1400/11/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-25, 1400/11/05**

Update count: **0**

Registration date

2022-01-25, 1400/11/05

Registrant information

Name

Asghar Marzban

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 1292

Email address

drmarzban@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of dexamethasone and injectable hydrocortisone in reducing the need for oxygen in preterm infants with high risk of bronchopulmonary dysplasia admitted to the NICU of Ayatollah Mousavi Hospital in Zanjan in 2021-22.

Public title

Comparative study of the effect of dexamethasone and injectable hydrocortisone in reducing the need for oxygen in preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Fetal age less than 33 weeks
The risk of bronchopulmonary dysplasia more than 60% according to the NICHD definition
Parental consent
Having received antenatal corticosteroid

Exclusion criteria:

Active systemic or pulmonary infection
Existence of congenital anomalies and metabolic diseases requiring surgery

Age

To **231 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be enrolled randomly in to one of the groups based on inclusion criteria. Randomisation sequence will be processed by Microsoft Excel program via (RANDBETWEEN) command and numbers 0 and 1 will be allocated to each group to choose the group of the subject.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be a double-blind study in which the doctor and the patient (patient's mother) will not know the type of drug received by the patient (dexamethasone or hydrocortisone).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Ayatollah Mousavi Hospital, Above Shahid Sabouti Boulevard, Gavazang Road, Zanjan, Iran.

City

Zanjan

Province

Zanjan

Postal code

4513956183

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.ZUMS.REC.1400.258

Health conditions studied

1

Description of health condition studied

Bronchopulmonary dysplasia

ICD-10 code

P27.1

ICD-10 code description

Bronchopulmonary dysplasia originating in the perinatal period

Primary outcomes

1

Description

Oxygen saturation

Timepoint

day 28 of birth

Method of measurement

pulse oximeter

Secondary outcomes

1

Description

Mechanical ventilation time

Timepoint

day 28 of birth

Method of measurement

Direct observation

2

Description

CPAP time

Timepoint

day 28 of birth

Method of measurement

Direct observation

3

Description

NICU hospitalization time

Timepoint

day 28 of birth

Method of measurement

Direct observation

4

Description

Pulse/Respiration rate

Timepoint

day 28 of birth

Method of measurement

Cardiac monitoring device

Intervention groups

1

Description

Intervention group Dexamethasone: Infants of the dexamethasone group will receive Dexamethasone injection from day 14 of birth (0.2 mg per kg body weight for the first 3 days and 0.1 mg per kg body weight for the next 4 days).

Category

Treatment - Drugs

2

Description

Intervention group Hydrocortisone: Infants of the hydrocortisone group will receive hydrocortisone injection from the 14th day of birth (1 mg per kg of body weight for 7 days).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi hospital

Full name of responsible person

Ebrahim Ramazannejad

Street address

Ayatollah Mousavi Hospital, Gavazang Road, Above Shahid Sabouti Boulevard, zanzan, iran.

City

Zanzan

Province

Zanzan

Postal code

4513956183

Phone

+98 24 3342 0651

Fax

+98 24 3313 1203

Email

Mousavihospital@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanzan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

Street address

Ayatollah Mousavi Hospital, Above Shahid Sabouti Boulevard, Gavazang Road, zanzan, iran.

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Province

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+98 24 3342 0651

Fax

+98 24 3313 1203

Email

Mousavihospital@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanzan 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

Zanzan University of Medical Sciences

Full name of responsible person

Asghar Marzban

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Drmarzban@zums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zanzan University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

Zanzan University of Medical Sciences

Full name of responsible person

Asghar Marzban

Position

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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