

# 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.

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

Zanzan University of Medical Sciences

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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**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Email**

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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