

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Investigation of the effect of low-dose hydrocortisone on neonatal respiratory status under mechanical ventilation

Protocol summary

Study aim

Investigation of the effect of low-dose hydrocortisone on neonatal respiratory status under invasive and non-invasive mechanical ventilation

Design

Clinical trial with control and parallel groups, randomized and single blind

Settings and conduct

This study will be conducted on 30 preterm neonates with gestational age of 37 weeks or lower hospitalized in the NICU ward of Ghaem hospital due to respiratory distress syndrome who cannot be disconnected from ventilator any longer than 14 days. Their disease is verified by a specialist and they will be randomly assigned to two groups of control and treatment. Both groups receive the same treatment but the intervention groups, in addition to Intravenous dexamethasone, receives hydrocortisone. Patient are unaware of groupings.

Participants/Inclusion and exclusion criteria

Inclusion criteria: preterm neonates who have been under mechanical ventilation for at least 14 days, informed consent of the patient's legal guardian.

Exclusion criteria: heart patients with failure, observable irregularities, neuromuscular diseases

Intervention groups

Intervention group: In this group, Intravenous dexamethasone 24 hours before until 48 hours after extubation with the dose of 0.5 mg/kg /day will be administered. In addition, hydrocortisone will be used for 5 days where in the first 3 days, it is administered twice daily with the dose of 0.5 mg/kg and in the next 2 days, once daily with the dose of 0.5 mg/kg. During the intervention, the neonate's blood pressure is controlled 3 times each 24 hours and the blood sugar is checked twice a day using glucometer. Control group: In this group, the common method will be used. Intravenous dexamethasone 24 hours before until 48 hours after extubation with the dose of 0.5 mg/kg /day will be

administered.

Main outcome variables

Status of need for mechanical ventilation; duration of connection to the ventilation device

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200721048155N1**

Registration date: **2020-08-01, 1399/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-01, 1399/05/11**

Update count: **0**

Registration date

2020-08-01, 1399/05/11

Registrant information

Name

Raheleh Faramarzi Garmroudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2496

Email address

faramarzigr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-05, 1398/11/16

Expected recruitment end date

2021-08-07, 1400/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of low-dose hydrocortisone on neonatal respiratory status under mechanical ventilation

Public title

The effect of low-dose hydrocortisone on neonatal respiratory status under mechanical ventilation

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Preterm neonates who have been under mechanical ventilation for at least 14 days Informed consent of the patient's legal guardian

Exclusion criteria:

Heart patients with failure Observable irregularities Neuromuscular diseases which influence respiratory effort

Age

From **7 days** old to **30 days** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants as well as the person who assigns them to the two groups are not aware of the type of treatment and the intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic Committee of Mashhad University of Medical Sciences

Street address

Ghoreyshi Building, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-02-04, 1398/11/15

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.139

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

respiratory status under mechanical ventilation

ICD-10 code

P27.8

ICD-10 code description

Other chronic respiratory diseases originating in the perinatal period

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

Status of need for mechanical ventilation based on level of oxygen needed

Timepoint

Before and during intervention and after disconnection from ventilation

Method of measurement

Patient monitoring device

2**Description**

Duration of connection to the ventilation device

Timepoint

Before intervention

Method of measurement

Counting the number of days patient was connected to the ventilation device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, Intravenous dexamethasone 24 hours before until 48 hours after extubation with the dose of 0.5 mg/kg /day will be administered. In addition, hydrocortisone will be used for 5 days where in the first 3 days, it is administered twice daily with the dose of 0.5 mg/kg and in the next 2 days, once daily with the dose of 0.5 mg/kg. During the intervention, the neonate's blood pressure is controlled 3 times each 24 hours and the blood sugar is checked twice a day using glucometer.

Category

Treatment - Drugs

2

Description

Control group: In this group, the common method will be used. Intravenous dexamethasone 24 hours before until 48 hours after extubation with the dose of 0.5 mg/kg /day will be administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Raheleh Faramarzi

Street address

Ghaem hospital, Ahmad Abad blvd, Taghiabad sq

City

Mashhad

Province

Razavi Khorasan

Postal code

9176999311

Phone

+98 51 3840 0000

Email

faramarzigr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

34591375

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Raheleh Faramarzi Garmroudi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Ahmad Abad Av, Ghaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9176999311

Phone

+98 51 3801 2496

Fax**Email**

faramarzigr@mums.ac.ir

Person responsible for scientific inquiries

Contact

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through an email to the corresponding author.

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

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

Mashhad University of Medical Sciences

Full name of responsible person

Raheleh Faramarzi Garmroudi

Position

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Latest degree

Subspecialist

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Province

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Postal code

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