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

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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

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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