Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The effect of using cold preservative serum on hypothermia in newborns with moderate to severe hypoxia ischemic encephalopathy

Protocol summary

Study aim
Determining the effect of using cold preservative serum on hypothermia in newborns with moderate to severe hypoxic ischemic encephalopathy

Design
They were divided into two groups: intervention and control. 50 samples were randomly divided into two groups. They were studied in the study.

Settings and conduct
Samples were selected from Imam Reza Hospital in Mashhad during 1396 to 1398 and a questionnaire was prepared using a blinded one that participants did not know how to do the plan.

Participants/Inclusion and exclusion criteria
Having written consent of parents after explaining and justifying them in the process of treatment and based on medical ethics standards, neonates with gestational age greater than 36 weeks and weighing more than 2500 grams have one of the following characteristics: 1) Apgar score less than 5 in 10 minutes after birth or need of the baby to continue the regenerative procedure (including ventilation with mask and intubation) until 10 minutes after birth or acidosis in the first hour after birth (PH in Cord blood or arterial blood or capillary blood is less than 7) or a base deficiency greater than 16 millimoles per liter in each of the blood samples in the first 60 minutes of birth

Intervention groups
Using the preserved serum to cool the temperature to 33-34 degrees Celsius in newborns with moderate to severe HIE that began at the first 6 hours of birth and continued until 72 hours after birth and then gradually warmed up The baby is between 8 and 12 hours to reach normal body temperature In the control group, newborns with moderate to severe HIE status are under current and current treatment in the neonatal intensive care units of the country without hypothermic treatment.

Main outcome variables
Creation of hypothermic therapy with central temperature 33 to 34 ° C using cold preservation serum

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190204042609N1**
Registration date: **2019-06-27, 1398/04/06**
Registration timing: **retrospective**

Last update: **2019-06-27, 1398/04/06**
Update count: **0**

Registration date
2019-06-27, 1398/04/06

Registrant information

Name
Mojtaba Adineh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3852 1121

Email address
saba671388@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-02-20, 1397/12/01

Actual recruitment start date
2017-03-21, 1396/01/01

Actual recruitment end date
2018-03-21, 1397/01/01

Trial completion date

2019-04-21, 1398/02/01

Scientific title
The effect of using cold preservative serum on hypothermia in newborns with moderate to severe hypoxia ischemic encephalopathy

Public title
Use of cold preservative in inducing hypothermia of newborns with encephalopathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Apgar score less than 5 in 10 minutes after the birth or need of the baby to continue the regenerative process (including ventilation with mask and intubation) until 10 minutes after birth or acidosis in the first hour after birth (PH in umbilical cord or arterial blood and Or capillary blood less than 7) or a base deficiency greater than 16 millimoles / liter in any of the blood samples within 60 minutes of the first birth Clinical manifestations of moderate to severe postpartum encephalopathy

Exclusion criteria:
Parental dissatisfaction at each stage of induction cooled therapy The infant's center temperature reaches more than 38 degrees Celsius Neonatal abnormalities require surgery Newborns with obvious anomalies require immediate intervention such as cyanatoid heart disease In case of possible complications of treatment, a newborn resuscitation, such as severe bradycardia associated with apnea

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was done simply so that the subjects were divided into two groups a and b according to the computer software table. The subjects were selected in each study and control group and their data were recorded in a questionnaire and blinded as one of the subjects was not aware of the two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
The analyst will be unaware of the intervention and control groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Qureishi Building- Daneshgah Ave- Mashhad- Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Approval date
2018-10-23, 1397/08/01

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.537

Health conditions studied

1

Description of health condition studied
ischemic hypoxic episma encephalopathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Infants with moderate to severe HIE

Timepoint
Duration 48 to 72 hours of birth

Method of measurement
Clinical-Biochemical

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Infants with moderate to severe HIE

Category
Treatment - Drugs

2

Description
Control group: Infants with moderate to severe HIE with conventional treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital, MAshhad University of Medical Sciences
Full name of responsible person
Mojtaba Adineh
Street address
Ibn Sina Ave- Imam Reza Hospital- MAshhad University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mojataba Adineh
Street address
Daneshgah Ave- Ghoreyshi bul- Mashhad- Iran
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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
Mojtaba Adineh
Position
أتخدشفخمخلهسف
Latest degree
Subspecialist
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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
A part of the questionnaire information that relates to patient information is shared.

When the data will become available and for how long
Start the access period after printing the results

To whom data/document is available
Available to academic and academic researchers

Under which criteria data/document could be used
After publishing it as a paper for the public and researchers from academic medical institutions

From where data/document is obtainable
ISI and Google

What processes are involved for a request to access data/document
In search sites, the use of asphyxiant words of infants - hypothermia in newborns

Comments