

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of therapeutic effects of induced local hypothermia in neonates with hypoxic - ischemic encephalopathy admitted to Fatemieh and Besat hospitals - Hamedan

Protocol summary

Summary

Introduction and background: Hypoxic-ischemic encephalopathy is one of the most important causes of permanent damage to brain tissue that redound to mortality and/or late sequelae such as cerebral palsy or delayed neural development. 15-20 percent of Hypoxic-ischemic encephalopathy (HIE) cases die during neonatal period and 25-30 percent of those who survive suffer from neural development problems such as cerebral palsy and mental retardation. Hypothermia or lowering temperature of brain or total body is a new and promising treatment. Objective: Present study was done to assess therapeutic effects of induced local hypothermia in hypoxic-ischemic encephalopathy (HIE) among neonates admitted to Fatemieh and Beasat hospitals of Hamedan. Design: Randomised (random blocks)- with a control group and two centre. Setting and conduct: A) Participants: neonates with at least one of following criteria that were in stage II of intensity of HIE: 1-Apgar score 5 or less at fifth minutes after birth 2- Fetal heart rate less than 60 beat per minutes 3- Prolonged metabolic acidosis 4-Need for positive pressure ventilation more than 1 min or delayed crying more than 5 min from birth 5- Occurrence of acute perinatal events Exclusion criteria: 1- Gestational age 35 weeks or less 2- Congenital anomalies Sample size: 36 neonates 18 in control group and 18 in case group Interventions: In the control group: Standard therapy such as O2 therapy and anticonvulsant as needed. In the intervention group: in addition to Standard therapy, induced head hypothermia by putting ice bag into oxyhood of neonates. Time of intervention: from admission in NICU to the end of sixth hour of life. Main outcome measures: evaluation of effect of hypothermia on: 1- mortality rate 2- incidence of convulsion in both groups 3- days of hospitalization 4- time of initiation of enteral feeding in both groups

General information

Acronym

not have

IRCT registration information

IRCT registration number: **IRCT201011065110N1**

Registration date: **2010-12-11, 1389/09/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-11, 1389/09/20

Registrant information

Name

Behnaz Basiri

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1821 3770

Email address

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Science

Expected recruitment start date

2008-06-29, 1387/04/09

Expected recruitment end date

2009-12-30, 1388/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effects of induced local hypothermia in neonates with hypoxic - ischemic encephalopathy admitted to Fatemieh and Besat hospitals - Hamedan

Public title

Effect of hypothermia on hypoxic-ischemic encephalopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: at least one of diagnostic criteria of HIE include: 1-APGAR score <5 at 5 minutes 2-Fetal heart rate <60 bpm 3-Prolonged metabolic acidosis(>1 hour) 4-Need of positive pressure ventilation>1 min or delay in crying >10 min of birth 5-Occurance of acute perinatal events Exclusion criteria: 1- Gestational age <35 weeks 2- Congenital anomalies

Age

To 6 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 36

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic committee of Hamedan University of Medical Science

Street address

Daneshgah boulevard- Faculty of medicine

City

Hamedan

Postal code

65157518

Approval date

2008-02-09, 1386/11/20

Ethics committee reference number

145839/9/35/16/پ

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

Hypoxic - ischemic encephalopathy

ICD-10 code

p91.6

ICD-10 code description

Hypoxic ischemic encephalopathy of newborn

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

Mortality

Timepoint

Total number of death at discharge time

Method of measurement

Physical examination

2**Description**

Convulsion

Timepoint

Total number of convulsion at discharge time

Method of measurement

Physical examination

Secondary outcomes**1****Description**

Time of initiation of enteral feeding

Timepoint

From beginning of intervention to discharge

Method of measurement

Days reported in patient sheet

2**Description**

Duration of Hospital stay

Timepoint

Beginning of intervention to discharge

Method of measurement

Days reported in patient sheets

Intervention groups**1****Description**

In intervention group, Induction of local hypothermia with putting ice bags in the oxyhood of patients

Category
Treatment - Other

2

Description
In control group: routine measures include O2 therapy , anticonvulsants .

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
NICU Fatemieh Hospital - Hamedan
Full name of responsible person
Behnaz Basiri
Street address
Fatemieh Hospital - Pasdaran Street
City
Hamedan

2

Recruitment center
Name of recruitment center
NICU- Besat Hospital
Full name of responsible person
Behnaz Basiri
Street address
Besat Hospital- Motahati Boulevard
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Science
Full name of responsible person
Ms. Ahmadkhani
Street address
Vice chancellor for research, Hamedan University of Medical Science- Daneshgah Boulevard
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Science
Proportion provided by this source
100

Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Hamedan University of Medical Science
Full name of responsible person
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Position
Neonatologist- Assistant Professor
Other areas of specialty/work
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Position

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Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty