Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of theraputic effects of induced local hypothermia in neonates with hypoxic - ischemic encephalopathy addmited 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)

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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 theraputic effects of induced local hypothermia in neonates with hypoxic - ischemic encephalopathy addmited 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
پ/145839/9/35/16

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 disharge time

Method of measurement
Physical examination

Secondary outcomes

1

Description
Time of initiation of enteral feeding

Timepoint
From biginning of intervention to discharge

Method of measurement
Days reported in patient sheet

2

Description
Duration of Hospital stay

Timepoint
Biginning of intervention to discharge

Method of measurement
Days reported in patient sheets

Intervention groups

1

Description

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

Category

Treatment - Other

2

Description

In control groop: rootne 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

Behnaz Basiri

Position

Neonatologist- Assistant Professor

Other areas of specialty/work

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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