

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

b.basiri@umsha.ac.ir

##### 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 Fatemeh 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**

Ethics 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**

Behnaz Basiri

**Position**

Neonatologist- Assistant Professor

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

NICU- Fatemieh Hospital- Pasdaran street

**City**

Hamedan

**Postal code**

6517789975

**Phone**

+98 81 1827 8080

**Fax**

+98 81 1838 2929

**Email**

b.basiri@umsha.ac.ir

**Web page address****Person responsible for scientific 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****Street address**

NICU - Fatemieh Hospital- Pasdaran street

**City**

Hamedan

**Postal code**

6517789975

**Phone**

+98 81 1827 8080

**Fax**

+98 81 1838 2929

**Email**

b.basiri@umsha.ac.ir; behnazbasiri@yahoo.com

**Web page address****Person responsible for updating data****Contact**

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**Fax**

+98 81 1838 2929

**Email**

b.basiri@umsha.ac.ir

**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*