Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Assesment of hypothermia compllication , in Two methods , head cooling and total body cooling in neonatal with birth asphyxia

Protocol summary

Summary

The aim of study is determination hypothermia side effect in two cooling methods: head cooling and total body cooling in neonates suffering from asphyxia.The study population of this study includes infants born with moderate or severe asphyxia And they are born in last 6 hours.Participated Infants are divided in2 groups. first group cooled with head cooling method during 1 hour until reached Core body temperature to(34-35),and the second group cooled with total bady cooling during 1 hour until reached Core body temperature to(32.5-33.5),and 72 hours kept at this temperature and then heated up gradually during 8-12hours. During 84 hours, every 4 hours, Bradycardia, apnea, cyanosis and seizuresis s, hypotension, thrombocytopenia, pulmonary hemorrhage, necrotic tissue damage,are measured and documented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204055168N2**
Registration date: **2012-07-03, 1391/04/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-07-03, 1391/04/13

Registrant information

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Maliheh Assadollahi
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Deputy for Research ,Tabriz University of Medical Sciences -College of Nursing and Midwifery, Tabriz University

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment of hypothermia compllication , in Two methods , head cooling and total body cooling in neonatal with birth asphyxia

Public title

Assesment of hypothermia complication in two methods , head cooling and total body cooling in neonatal with birth asphyxia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria 1. Infants with gestational age 35 weeks or more, 2. Six – hour infant or less than that 3. Infants weight more than 1800g 4. Apgar score 6 or less within 10 minutes from birth 5. Cord of pH 7 or less alkali deficiency 12 or less 6. Hypoxia ischemic encephalopathy moderate or severs 7. Infants with normal respiratory condition and infants under

ventilation Exclusion criteria: 1. Infants with bradycardia less than 70, 2. Infants with hypotension any response to medication, 3. Infants with severe pulmonaryhemorage, 4. Coagulation disorders, 5. Resistance hypoxia,

Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
- Tabriz University of Medical Sciences - Research
City
Tabriz
Postal code
51745-347
Approval date
2012-03-12, 1390/12/22
Ethics committee reference number
918

Health conditions studied

1

Description of health condition studied
neonates with moderate to severe birth asphyxia
ICD-10 code
G90-G99
ICD-10 code description
Diseases of the nervous system

Primary outcomes

1

Description
Apnea
Timepoint
Every 4 hours for 84 hours
Method of measurement
Color Cyanosis, bradycardia, and arterial oxygen saturation less than 70% when using pulse oximetry or monitor device

2

Description
Bradycardia
Timepoint
Every 4 hours for 84 hours
Method of measurement
Using the monitor device

3

Description
convulsion
Timepoint
Every 4 hours for 84 hours
Method of measurement
Using clinical symptoms and the presence of waves with short wave length and high frequency in the EEG

4

Description
Hypotension
Timepoint
Every 4 hours for 84 hours
Method of measurement
Using the Monitor

5

Description
Thrombocytopenia
Timepoint
Every 24 hours for 84 hours
Method of measurement
CBC test

6

Description
Necrotic skin damage
Timepoint
Every 4 hours for 84 hours
Method of measurement
Clinical observation of ecchymosis, bruises, wounds deep and necrotic skin

7

Description

Pulmonary hemorrhage

Timepoint

Every 4 hours for 84 hours

Method of measurement

Using clinical signs and symptoms of pulmonary hemorrhage on chest radiograph confirmed by physician

Secondary outcomes

empty

Intervention groups

1

Description

Thirty neonatal with moderate and severe asphyxia cooled with head cooling method to achieve the target temperature (rectal 34-33) for 1 hour,and held for 72 hours at this temperature, The neonatal are heated gradually during the 8-12 time to reach the normal temperature (36.5).

Category

Treatment - Devices

2

Description

In the second group thirty neonatal with moderate and severe asphyxia cooled with total bady cooling method,using Turn off Varmr and cold water bag (15-10)° C,to achieve the target temperature (rectal 32.5-33.5) for 1 hour,and held for 72 hours at this temperature, Then neonatal are heated gradually during the 8-12 time to reach the normal temperature (36.5).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Alzahra hospital

Full name of responsible person

Dr.Abdollah Janatdost

Street address

Alzahra hospital, baghshomal crossroad, Artesh street, Tabriz.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research of Nursing and Midwifery faculty, Tabriz University of Medical Sciences

Full name of responsible person

maliheh assadollahi

Street address

Pediatric Department of nursing and midwifery faculty

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research of Nursing and Midwifery faculty, Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Maliheh Assadollahi

Position

MSc in pediatric Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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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