

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the use of plastic caps with cotton caps in the delivery room to prevent hypothermia in extremely & very premature infants

Protocol summary

Study aim

Comparison of the use of plastic caps with cotton caps in the delivery room to prevent hypothermia in very premature infants in the special care department of Imam Khomeini Hospital.

Design

A clinical trial with a control group , randomization as Parallel two groups (intervention group and control group) and two block permuted (for each group two blocks of 28-32 weeks and 25-27 weeks), randomization by the list of numbers generated by the computer in closed envelopes and seen by the relevant resident and placing the baby in the relevant group

Settings and conduct

Placement of infants born less than 32 weeks in the maternity hospital or the operating room of Imam Khomeini Teaching Hospital in Sari in two intervention groups receiving plastic caps and the control group receiving fabric caps.

Participants/Inclusion and exclusion criteria

Entry requirements: All infants less than 32 weeks
Conditions of non-entry: Congenital anomalies ,
Congenital problems characterized by defects in the skin , infants who do not need to start resuscitation according to the newborn resuscitation guidelines, including infants under 22 weeks , weight under 400 grams, anencephalic infants, infants with life-threatening anomalies diagnosed by a doctor , infants born to mothers with covid-19 , LGA, IUGR, SGA babies according to the pregnancy ultrasound report or based on the weight-for-gestational age curve
Premature infants , infants 24 weeks and less , infants who need phototherapy at the beginning of hospitalization.

Intervention groups

The use of plastic caps in 34 premature infants 25 to 32 weeks in the intervention group and the use of cloth caps in 34 premature infants 25 to 32 weeks in the control group to prevent hypothermia

Main outcome variables

hypothermia during hospitalization and post stabilization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091201002801N5**

Registration date: **2023-02-09, 1401/11/20**

Registration timing: **prospective**

Last update: **2023-02-09, 1401/11/20**

Update count: **0**

Registration date

2023-02-09, 1401/11/20

Registrant information

Name

Roya Farhadi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 3018

Email address

rfarhadi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the use of plastic caps with cotton caps in the delivery room to prevent hypothermia in extremely & very premature infants

Public title

Comparison of the use of plastic caps with cotton caps in the delivery room to prevent hypothermia in extremely & very premature infants

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All infants less than 32 weeks who are born in the maternity hospital or operating room of Imam Khomeini Teaching Hospital in Sari

Exclusion criteria:

Congenital anomalies in infants Congenital problems characterized by defects in the newborn's skin, such as gastroschisis, epidermolysis bullosa, omphalocele, and myelomeningocele infants who do not need to start resuscitation according to the newborn resuscitation guidelines include infants under 22 weeks, weighing less than 400 grams, anencephalic infants, infants with anomalies contrary to life as diagnosed by a doctor. infants 24 weeks and less infants LGA, IUGR, SGA according to pregnancy ultrasound report or based on the weight-for-gestational-age curve of premature infants infants who need phototherapy at the beginning of hospitalization infants born to mothers with covid-19

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done just before the delivery of the infant. Randomization is done as parallel two groups (intervention group and control group) and as two block permuted (for each group two blocks of 28-32 weeks and 25-27 weeks) to remove the intervening factor of gestational age. Randomization is created by the list of numbers generated by the computer and placed in sealed envelopes. Right after delivery, the resident is seen in the resuscitation team and the baby is placed in the appropriate group. For multiple births, each child is randomized separately.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

So far, no study has been conducted in the field of covering the head with a plastic cap, especially at a very low gestational age in premature infants of 25 to 32 weeks.

Secondary Ids

empty

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

Pasdaran Boulevard, Boali Sina Hospital

City

sari

Province

Mazandaran

Postal code

4815838477

Approval date

2023-02-05, 1401/11/16

Ethics committee reference number

IR.MAZUMS.REC.1401.490

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

Hypothermia of newborn

ICD-10 code

P80

ICD-10 code description

Hypothermia of newborn

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

Hypothermia at the time of hospitalization and post stabilization

Timepoint

Measurement of axillary temperature of newborns at birth and one hour after hospitalization and stabilization

Method of measurement

mercury thermometer

Secondary outcomes

1

Description

Hospitalization days, presence or absence of death, patent ductus arteriosus, retinopathy of prematurity, intraventricular hemorrhage, sepsis, necrotizing enterocolitis, need for surfactant and duration of respiratory support

Timepoint

During hospitalization

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: infants who receive plastic caps.

Category

Prevention

2

Description

Control group: infants who receive cotton caps.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari

Full name of responsible person

Roya Farhadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahimnezhad

Street address

Moalem Ave, Vice President of Research and

Technology

City

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Mazandaran

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4815733971

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pajhooeshi@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Roya Farhadi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It will be published later in the form of a controlled clinical trial article.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The information and results of the study are shared in the form of a clinical trial article.

When the data will become available and for how long

After finishing the research project in the form of an article

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In the form of a scientific article

From where data/document is obtainable

A magazine that will be published later

What processes are involved for a request to access data/document

After printing the article

Comments

-

Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

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Latest degree

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