Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Compare the effect of two methods of plastic wrap and blanket on body temperature, heart rate and oxygen saturation in preterm infants under radiant warmer: A randomized controlled cross over clinical trial single blind.

Protocol summary

Summary

This study is a randomized, single blind crossover clinical trial on premature infants in NICU of the Tabriz Taleghani hospital since birth will take place are . Eligible subjects were randomly assigned into one of two groups of 80 neonate in the study were. selection (40 infants in group 1 and 40 infants in group 2). In both groups, the duration of two days per day, measured in hours (8-9-12-15-18-21) will be done. The crossover clinical trial on premature infants who hospitalized in NICU of Tabriz Taleghani hospital from birth time. 80 eligible neonates were randomly assigned into two groups (40 infants in group 1 and 40 infants in group 2). Duration of study in both groups will be two days and measurements will be done at (8-9-12-15-18-21) every day. The first measurement will be done at 8 AM. After wash out period (1hour) the second measurement will be done at 9 am and then every 3 hours to 9PM. Infants in group 1, from 8 AM to 9 AM for one hour will be covered with slipcover (wash out time to relieve the effects of previous coverage) and will be covered with plastic wrap (neck to bottom) from 9 AM until 8 AM the next day for a period of 23 hours. The second day to change the covers, infants will be covered with slipcover at 8 AM until 9 AM (for one hour, as wash out time). Then infants will be covered with blanket from neck to bottom from 9 AM to 8 AM the next day for 23 hours. The infants in group 2, the first day will be covered with blanket and then will be covered with plastic wrap the second day and the measurement will be done the same manner. first measurement before starting work at 8 am and will be wash out . after the second measurement time at 9 am and then every 3 hours to 21 oclock. Infants in group 1, from 8 am to 9 am for one hour are covered with slipcover(over a period of time to wash out and relieve the effects of previous coverage) and from 9 am until 8 am the next day for a period of 23 hours from the covered neck to the bottom with plastic wrap, on the second day at 8 am until 9 am (for one hour) in the neck to be pulled down bedding (wash out) then the neonate for hours 9 am to 8 am for 23 hours, from the neck down covered with blanket. The infants in group 2, the first day with blanket and the second day with plastic wrap covered and methods of measurement, such as Group 1.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407218315N11**
Registration date: **2016-01-18, 1394/10/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-18, 1394/10/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date
2015-12-22, 1394/10/01
Expected recruitment end date
2016-05-21, 1395/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Compare the effect of two methods of plastic wrap and blanket on body temperature, heart rate and oxygen saturation in preterm infants under radiant warmer: A randomized controlled cross over clinical trial single blind.

Public title
Comparison of blanket and plastic wrap on the body temperature of premature infants.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Infants with 28 to 30 weeks of gestation, birth weight of 800 to 1250 grams, caring under the radiant warmer, being on the second or third day of birth, Respiratory care with Nasal CPAP or HFNC. Exclusion criteria: neural tube defects, congenital skin diseases, congenital heart diseases, congenital malformations of abdominal wall (omphalocele, gastroschisis), diagnosis of neonatal sepsis, metabolic disorders, infants referred from other centers, surgery, Intrauterine growth retardation (IUGR) , born from mothers with fever(fever greater than 38.5 ° C), died during the study, discharged during the study (with personal satisfaction), being under ventilation, lack of parental consent to continue study, phototherapy, exchange blood, body temperature greater than 38 and less than 36 °C , heart rate less than 70 and more than 200, arterial oxygen saturation less than 80%.
Age
From **7 months** old to **7 months** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Azadi Street, Golgasht Street, Tabriz University of Medical Sciences
City
Tabriz
Postal code
00984134796770
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
TBZMED.REC.1394.846

Health conditions studied

1

Description of health condition studied
Effects of Covers on hypothermia
ICD-10 code
P81.9
ICD-10 code description
Disturbance of temperature regulation of newborn, unspecified

Primary outcomes

1

Description
Determination and comparison of the body temperature, heart rate and arterial oxygen saturation.
Timepoint
One hour before and after the washout period, then every three hours for 12 hours.
Method of measurement
Digital thermometer and monitoring devices

Secondary outcomes

1

Description
Complications, each of the covering
Timepoint
Every three hours during the 48 hours of study time
Method of measurement
observation, digital thermometers, control devices

Intervention groups

1

Description
Infants in group 1 from 8 to 9 am for an hour of their neck down, covered with slipcover(over a period of time to wash out and relieve the effects of previous coverage) and then from 9 am until 8 am the next day for a period of 23 hours from the neck down covered with plastic wrap, then the same time, from 8 to 9 am for an hour from the neck to the bottom is covered with slipcover(over time wash out and gutting work intervention previous) then the baby from 9 am until 8 am the next day for a period of 23 hours, from the neck down covered with blanket(Technique routine is blanket. Technique Intervention is the use of plastic wrap. During the wash out is the use of slipcover).

Category
Other

2

Description
Infants in group 2 from 8 to 9 am for an hour of your neck down, covered with slipcover(over a period of time to wash out and relieve the effects of previous coverage) and then from 9 am until 8 am the next day for a period of 23 hours from the neck down covered with a blanket, then the same time, from 8 to 9 am for an hour of your neck down, covered with slipcover(over time wash out and the destruction of intervention previous) then the baby from 9 am until 8 am the next day for a period of 23 hours, from the neck down covered with plastic wrap(Technique routine is blanket. Technique Intervention is the use of plastic wrap. During the wash out is the use of slipcover).

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani teaching hospitals

Full name of responsible person
Maryam Peyghami

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Str. Rahahan

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Rashidi

Street address
Azadi Street - Street Golgasht - Tabriz University of Medical Sciences

City
Tabriz

Grant name

Grant code / Reference number
TBZMED.REC.1394.846

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

Title of funding source
Research 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
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Full name of responsible person
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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