

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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 o'clock. 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

##### Name

Leila Valizadeh

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

valizadehl@tbzmed.ac.ir

#### 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

##### Street address

Str. Rahahan

##### City

Tabriz

## 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Maryam Peyghami

##### Position

MS nursing student

##### Other areas of specialty/work

##### Street address

south shariatist., Tabriz Faculty of Nursing and Midwifery

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##### Postal code

5138947977

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## Person responsible for scientific inquiries

#### Contact

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Dr. Leila Valizadeh

##### Position

Associate Professor

##### Other areas of specialty/work

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Maryam Peyghami

**Position**

MS nursing student

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

south shariatist, Tabriz Faculty of Nursing and  
Midwifery

**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*