

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of bath on clinical outcomes in preterm infants: a randomized controlled trial

Protocol summary

Summary

The aim of this study is to determine the impact of bath on clinical outcomes in preterm infants. It is a single blinded study, so that the researchers were not blinded, only to be blinded by the executive nurse. In this study, cases will be randomly divided into two groups; intervention and control group. Infants in the control group will receive only the routine skin care which is common in that unit and in Intervention group in addition to routine care, every three days, each time for 5 minutes; infants will be bathed in the bathtub by two helping researchers. In total during the study infants in the intervention group will experience this type of bath just three times. During the entire study period, physiological parameters (body temperature, oxygen saturation and pulse rate) in intervention days; '10 minutes before and 10 minutes after bathing intervention' and desired outcome (weight) daily will be measured and recorded in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306164617N7**

Registration date: **2013-06-28, 1392/04/07**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-06-28, 1392/04/07

Registrant information

Name

Mahnaz Jabraeili

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

jabraeilim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-09-01, 1392/06/10

Expected recruitment end date

2013-12-01, 1392/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of bath on clinical outcomes in preterm infants: a randomized controlled trial

Public title

Effect of bath on clinical outcomes in preterm infants: a randomized controlled trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age of infants 34-37 weeks of gestation; infant's age at study entry should be 72 hours after birth; no chromosomal abnormalities and congenital anomaly; 5-minute Apgar score of 7; Physiologic stability and no need to oxygen; not having any discharge or bleeding at the site of the umbilical cord; exclusive breast feeding; lack of feeding for at least half an hour before bath; not receiving drugs that affect

the level of consciousness, like: phenobarbital; not having a brain hemorrhage, asphyxia, kernicterus, and diseases leading to loss of consciousness; having a baseline baby's body temperature that should be at 36.5 ° C and parent consent for participating of infant in the study. Exclusion criteria: occurrence of symptoms such as apnea and cyanosis, or have any ill during bathing; baby bathe in the intervention and control groups by staff without notice; washing any parts of baby's body in the intervention and control groups for any reason (including changing diapers, etc.); at least one hour before intervention; tendency of control infant's mother to bath her baby; the baby's mother's unwillingness to continue the study in the intervention group (giving the baby a bath); low frequency of infants' bathing in the intervention group during the study (less than two).

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tabriz University of Medical Sciences Ethics Committee

Street address

Deputy of Research, Tabriz University of Medical Sciences ,Golgasht street , Tabriz, East Azarbaijan

City

tabriz

Postal code**Approval date**

2013-07-22, 1392/04/31

Ethics committee reference number

9248

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

Bath outcome in preterm infants

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Changes of body temperature of preterm infants

Timepoint

On intervention days in 10 minutes before and 10 minutes after the bath

Method of measurement

Using a mercury thermometer

Secondary outcomes**1****Description**

O2 saturation of preterm infants

Timepoint

On intervention days in 10 minutes before and 10 minutes after the bath

Method of measurement

Using a novamatrix pulse oximeter

2**Description**

Heart rates of preterm infants

Timepoint

On intervention days in 10 minutes before and 10 minutes after the bath

Method of measurement

Using a novamatrix pulse oximeter

3**Description**

Weight gain preterm infant

Timepoint

Throughout the study period; daily

Method of measurement

Using a Seca Scale

Intervention groups**1****Description**

Intervention infants, every three days, each time for 5 minutes, will be bathed in the bathtub by two helping researchers. In total during the study these infants will experience this type of bath just three times.

Category

Other

2

Description

Infants in the control group will receive only the routine skin care which is common in that unit

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Educational Center Affiliated Medical Sciences of Tabriz;Iran

Full name of responsible person

Ameneh Safaei

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Ostad Rahimi

Street address

Research Department, Central Building , Golgasht , Tabriz Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of 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

Ameneh Safaei

Position

Nursing Master of Science Student

Other areas of specialty/work

Street address

Shariety South St. Faculty of Nursing & Midwifery, Tabriz, Iran

City

Tabriz

Postal code

Phone

+98 41 1380 3738

Fax

Email

b.a.safaei1365@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahnaz Jabraeili

Position

MS, Faculty member

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Shariati South Street , Tabriz , Iran Tabriz

City

Tabriz

Postal code

Phone

+98 41 1479 6770

Fax

Email

jabraeilim@tbzmed.ac.ir; jebraeilim@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ameneh Safaei

Position

Nursing Master of Science Student

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Shariati South Street , Tabriz, Iran Tabriz

City

Tabriz

Postal code

Phone

+98 41 1380 3738

Fax

Email

b.a.safae1365@gmail.com

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