Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity

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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 novametrix 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 novametrix 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
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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
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Research Department, Central Building , Golgasht , Tabriz Tabriz
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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

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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