Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparison between the effects of swaddled bathing and conventional bathing on some physiological and behavioral parameters among the preterm neonates in neonatal intensive care unit in a Shiraz Medical Sciences University hospital.

Protocol summary

Summary

1)Objectives: Comparing the effects of swaddle bathing and conventional bathing on some physiological and behavioral parameters among the preterm neonates. 2) Design: single-blind randomized clinical trial 3) Setting and conduct: 50 premature infants who are eligible for the study are divided by simple randomized sampling allocation into two experimental and control groups. The infants in the experimental group are bathed using the swaddled bathing method and the infants in the control group are bathed using the conventional bathing method. Body temperature, heart rate, respiratory rate, and blood oxygen saturation are measured 10 minutes before and 10 minutes after the bathing by a nurse who is kept uninformed about the study and its assumptions. To record the behavioral responses, the infant's face is captured in close-up during the bathing and the films are interpreted by an observer without knowledge of the intervention type. Finally, the changes in the physiological and behavioral parameters of the two groups are compared. 4) Participants including major eligibility criteria: The preterm neonates in the neonatal intensive care unit; Major inclusion criteria include gestational age of 30–36 weeks, postnatal age of 7-30 days, not using sedatives and skeletal muscle relaxant drugs, no major congenital, chromosomal or neurological abnormalities, no evidence of grade II or higher intraventricular hemorrhage, and the stability of physiological parameters in the infant. Major exclusion criteria include the occurrence of seizures or symptoms of physiological instability in the infant, and parents' unwillingness to continue cooperating in research. 5) Interventions: Using the conventional bathing method in the control group and the swaddled bathing method in the experimental group, measuring physiological parameters before and after the bathing, recording and interpreting the behavioral responses during the bathing. 6) Main outcome measures (variables): Body temperature, heart rate, respiratory rate, blood oxygen saturation, and behavioral responses.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090814594N1**
Registration date: **2014-01-03, 1392/10/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-01-03, 1392/10/13

Registrant information

Name
Maryam Paran
Name of organization / entity
Shiraz University of Medical Sciences - Hazrat-e-Fatemeh Nursing and Midwifery Faculty
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date
2013-07-17, 1392/04/26
Expected recruitment end date
2014-01-16, 1392/10/26
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison between the effects of swaddled bathing and conventional bathing on some physiological and behavioral parameters among the preterm neonates in neonatal intensive care unit in a Shiraz Medical Sciences University hospital.

Public title
A comparison between the effects of swaddled bathing and conventional bathing on physiological and behavioral parameters among the preterm neonates.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion Criteria : Gestational age of 30–36 weeks; postnatal age of 7-30 days; not using sedatives and short- or long-acting skeletal muscle relaxant drugs; not having substance abuse issues and no sedative drug use by the mother; no major congenital, chromosomal or neurological abnormalities; no need for surgery; no severe growth problems from birth; no evidence of grade II or higher intraventricular hemorrhage; stability of physiological parameters in the infant. Exclusion Criteria: Occurrence of seizures in the infant; symptoms of physiological instability in the infant; parents' unwillingness to continue cooperating in research.
Age
To **1 year** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
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
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand Street, Shiraz
City
Shiraz
Postal code
Approval date
2013-07-16, 1392/04/25
Ethics committee reference number
92-6606

Health conditions studied

1

Description of health condition studied
Physiological and behavioral parameters of premature infants in swaddled bathing and conventional bathing
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Temperature
Timepoint
10 minutes before and 10 minutes after the bathing
Method of measurement
Axillary mercury thermometer

2

Description
Heart rate
Timepoint
10 minutes before and 10 minutes after the bathing
Method of measurement
Pulse oximetry

3

Description
Blood oxygen saturation
Timepoint
10 minutes before and 10 minutes after the bathing
Method of measurement
Pulse oximetry

4

Description
Respiration rate

Timepoint
10 minutes before and 10 minutes after the bathing
Method of measurement
Observation

5

Description
Behavioral responses
Timepoint
During the bathing
Method of measurement
Video camera

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, infants are bathed using the swaddled bathing method. In this method, the infant is swaddled with a soft towel such that the arms and legs remain in a flexed position and bathed in a tub using the swaddled bathing method.
Category
Prevention

2

Description
In the control group, the infants are bathed using the conventional method in which different parts of the infant's body are washed under faucet. The infant's body is then covered and his/her head and face are washed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez hospital
Full name of responsible person
Maryam Paran
Street address
Hafez hospital, Abiverdi Street, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, shiraz University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Hatam
Street address
Shiraz University of Medical Sciences, Zand Street, Shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, shiraz 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
Shiraz University of Medical Sciences - Hazrat-e-Fatemeh Nursing and Midwifery Faculty
Full name of responsible person
Maryam Paran
Position
Neonatal Intensive Care Nursing Master of Science Student
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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