

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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

Country

Iran (Islamic Republic of)

Phone

00

Email address

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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

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

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Full name of responsible person

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Position

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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