

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing the effect of tub and swaddled bathing method on premature neonate's stress behavior responses in nicu

Protocol summary

Study aim

Comparing the effect of tub and swaddled bathing method on premature neonate's stress behavior responses in NICU

Design

In this study, 80 premature infants who have inclusion criteria were randomly divided into two equal groups of 40 subjects with the same conditions. In group 1, the babies were bathed by swaddled bathing method and in group 2, babies bathed by tube bathing method.

Settings and conduct

In this double-blind study, first, referring to the Ayatollah Rouhani Hospital, a referral letter from Babol University of Medical Sciences, and after coordination with the boss of the hospital and the NICU's head nurse. After explaining the purpose of the research and explaining the method of work to the parents, informed consent will be obtained from the parent of each baby. 80 premature infants who have inclusion criteria were randomly divided into two equal groups of 40 subjects with the same conditions. In group 1, the babies were bathed by swaddled bathing method and in group 2, babies bathed by tube bathing method. In this study, a group of neonates are bathed by swaddled bathing method and the other group are bathed by tube bathing method with a standard detergent solution in a NICU with an ambient temperature of between 26-27 ° C and water at a temperature between 37-37.5 ° C, They are bathed by the researcher. In the swaddled bathing group, the neonates are wrapped in a soft towel with their arms and legs kept in a flexed midline position they are fully immersed from the shoulders down in a plastic tub 9 cm depth of warm water. The eyes were first washed with a soft cotton cloth and warm water from the inner corner of the eye. The baby's limb are washed slowly with a mild detergent and soft cotton cloth and then washed off the leg and genital area. The other part of the baby's body is washed so that the hair and the baby's head are washed off at the end. The baby is put in a dry towel. After

warming, under radiant transferred to the incubator. tub bathing group in this method, the baby is completely immersed in warm water in a plastic tub with a depth of 9 cm. Then the baby's body is washed with a cloth and a mild detergent. Then the head and hair are washed and wrapped in a towel and after warming under radiant transfer to the incubator. The duration of bathing filmed by researcher and these film reviewed by some one other than researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age less than 37 week, no major congenital abnormality, not using sedatives or skeletal muscle relaxant, age between 3-54 day and exclusion criteria; Major congenital abnormality, sepsis, surgery, seizure, treatment with sedatives and muscle relaxant, mechanical ventilation, risk of aspiration, agitation, metabolic disorders and Intraventricular hemorrhage

Intervention groups

In this study, a group of neonates are bathed by swaddled bathing method and the other group are bathed by tube bathing method with a standard detergent solution in a NICU with an ambient temperature of between 26-27 ° C and water at a temperature between 37-37.5 ° C, They are bathed by the researcher. In the swaddled bathing group, the neonates are wrapped in a soft towel with their arms and legs kept in a flexed midline position they are fully immersed from the shoulders down in a plastic tub 9 cm depth of warm water. The eyes were first washed with a soft cotton cloth and warm water from the inner corner of the eye. The baby's limb are washed slowly with a mild detergent and soft cotton cloth and then washed off the leg and genital area. The other part of the baby's body is washed so that the hair and the baby's head are washed off at the end. The baby is put in a dry towel. After warming, under radiant transferred to the incubator. tub bathing group in this method, the baby is completely immersed in warm water in a plastic tub with a depth of 9 cm. Then the baby's body is washed with a cloth and a mild detergent. Then the head and hair are washed and

wrapped in a towel and after warming under radiant transfer to the incubator

Main outcome variables

newborn's Stress behavior during bathing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171128037658N1**

Registration date: **2018-01-24, 1396/11/04**

Registration timing: **retrospective**

Last update: **2018-01-24, 1396/11/04**

Update count: **0**

Registration date

2018-01-24, 1396/11/04

Registrant information

Name

Sakineh Mokhtari naseri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5224 4076

Email address

s.mokhtar@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-31, 1396/03/10

Expected recruitment end date

2018-01-10, 1396/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of tub and swaddled bathing method on premature neonate's stress behavior responses in nicu

Public title

effect of tub and swaddled bathing on premature neonate's stress

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age less than 37w, no major congenital abnormality, not using sedatives or skeletal muscle relaxant, age between 3-54 days

Exclusion criteria:

Major congenital abnormality, sepsis, surgery, seizure,

treatment with sedatives and muscle relaxant, mechanical ventilation, risk of aspiration, agitation, metabolic diseases and IVH

Age

From **3 days** old to **54 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **40**

In this study preterm neonates divided in two groups of 40 neonates that that bathing by tub and swaddled method.

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study preterm neonates divided in two groups of 40 neonates that that bathing by tub and swaddled method. The duration of bathing filmed by researcher and these film check by some one other than researcher. In this research the evaluator is blinded.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, the film is reviewed by someone other than the researcher. stress behavior response during bathing are calculated every 10 second

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of babol medical medical sciences

Street address

Babol medical university Ganj afrooz avenue

City

babol

Province

Mazandaran

Postal code

4661946581

Approval date

2017-12-07, 1396/09/16

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

newborn's stress behavior

ICD-10 code

Z74

ICD-10 code description

Problems related to care provider dependency

Primary outcomes

1

Description

Stress behavior

Timepoint

The stress behavior is calculated only during the bathing , which last less than 10 minutes.

Method of measurement

by the film that taken by the researcher during bathing, it evaluate by someone other than the researcher and the number of these behaviors is calculated every 10 seconds according to the checklist.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group 1 infants are bathed by swaddled bathing method.

Category

N/A

2

Description

Intervention group: Group 2 is bathed by by immersion tubbathing method

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

ayatollah rohani hospital

Full name of responsible person

sakineh mokhtari naseri

Street address

Babol ganj afrooz avenue next to ghadir pool roohani hospital

City

babol

Province

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4661946581

Phone

+98 11 5224 4076

Email

s.mokhtari@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abadan University of Medical Sciences

Full name of responsible person

sakineh mokhtari naseri

Street address

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babol

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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

Abadan University of Medical Sciences

Proportion provided by this source

1

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

sakineh mikhtari naseri

Position

master science student in neonatal intensive care

feild

Latest degree

Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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master science in neonatal intensive care feild
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available