

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of mother's supportive interventions on preterm infant stress during swaddle bath: randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of mother's supportive interventions on preterm infant stress during swaddle bath

Design

Randomized controlled clinical trial with control group, Randomized with Randlist software , single blind With 50 samples

Settings and conduct

Nicu of Ahar Hospital, Entry of samples according to the inclusion criteria Obtaining written consent, Baby bathing was performed in the presence of the mother, and supportive measures were taken before and during the bathing by the mother, and newborn stress was measured by the Newborn stress scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) infants with gestational age of 30-37 weeks 2) birth weight 1500 g or more 3) neonate age 3 days or more. 4) Doctor's order for Bathing the baby 5) body temperature ranging from 36.5 to 37.5 °C 6) stable vital signs and no oxygen required 7) parental consent 8) Non-feeding baby at least one hour before bath. Exclusion criteria: 1) Symptoms such as apnea and cyanosis or any illness during bathing 2) Seizure or physiological instability 3) Use of sedatives and muscle relaxants 4) Chromosomal abnormality or congenital malformations 5) IVH

Intervention groups

In the intervention group, the infant will be supported 8 minutes before the bath and during the bath by the mother by the gentle touch of the face, kissing and talking. In the control group, the baby will be bathed by the researcher in the presence of the mother, and supportive measures will be taken by the mother.

Main outcome variables

stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100823004617N15**

Registration date: **2019-11-12, 1398/08/21**

Registration timing: **retrospective**

Last update: **2019-11-12, 1398/08/21**

Update count: **0**

Registration date

2019-11-12, 1398/08/21

Registrant information

Name

Mahnaz Jabraeili

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-31, 1397/05/09

Expected recruitment end date

2019-01-29, 1397/11/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mother's supportive interventions on preterm infant stress during swaddle bath: randomized controlled clinical trial

Public title

The effect of mother's supportive interventions on preterm infant stress during swaddle bath: randomized controlled clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

infants with gestational age of 30-37 weeks. birth weight 1500 g or more neonate age 3 days or more Doctor's order for Bathing the baby body temperature ranging from 36.5 to 37.5 °C stable vital signs and no oxygen required. parental consent Non-feeding baby at least one hour before bath

Exclusion criteria:

Symptoms such as apnea and cyanosis or any illness during bathing Seizure or physiological instability Use of sedatives and muscle relaxants Chromosomal abnormality or congenital malformations IVH

Age

From **3 days** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected by available method and randomly divided into intervention and control groups using Rand List software. To completely hide the allocation, the block sizes will not be the same and the letters A and B will be placed in the envelope respectively and the first baby will be given envelope number 1 and envelope number respectively. After opening the envelope, the type of group will be specified.

Blinding (investigator's opinion)

Not 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

Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

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East Azarbaijan

Postal code

5138947979

Approval date

2019-07-14, 1398/04/23

Ethics committee reference number

IR.TBZMED.REC.1398.429

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

Stress

Timepoint

8 minutes before starting until 5 minutes after bath

Method of measurement

Newborn stress scale (NSS) tool

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, the infant will be supported 8 minutes before the bath and during the bath by the mother by the gentle touch of the face, kissing and talking.

Category

Other

2

Description

In the control group, the baby will be bathed by the researcher in the presence of the mother, and supportive measures will be taken by the mother during the bath.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bagherololum Ahar Hospital Affiliated Medical Sciences of Tabriz,Iran

Full name of responsible person

Nasim soltani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Tabriz University of Medical Sciences

Proportion provided by this source

100

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**

Tabriz University of Medical Sciences

Full name of responsible person

Nasim soltani

Position

Nursing Master of Science student

Latest degree

Bachelor

Other areas of specialty/work

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Phd.Faculty member

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Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

What processes are involved for a request to access data/document

Comments