

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

jabraeilim@tbzmed.ac.ir

##### 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

#### Province

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

**Street address**

Bagherololum Ahar Hospital

**City**

Ahar

**Province**

East Azarbaijan

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Rashidi

**Street address**

Research\_Department - Central Building- Golgasht-Tabriz

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**Province**

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+98 41 3335 5921

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info@medfac.tbzmed.ac.ir

**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**

Nursery

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Shariati South St, Faculty of Nursing and Midwifery,Tabriz, Iran

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soltani.n95@gmail.com

**Web page address**

<https://nursing.tbzmed.ac.ir/>

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mahnaz Jabraeli

**Position**

Phd.Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pediatrics

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

Soltani.n95@gmail.com

**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**

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**When the data will become available and for how long**

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**To whom data/document is available**

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**Under which criteria data/document could be used**

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**From where data/document is obtainable**

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

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**Comments**