

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The effect of Swaddling bathing on oxygen needs and physiologic parameters (body temperature, HR and RR) among premature neonates with chronic lung disease (CLD): a randomized clinical trial

Protocol summary

Study aim

The main objective: The effect of Swaddling bathing on oxygen needs and physiologic parameters (body temperature, HR and RR) among premature neonates with chronic lung disease (CLD): a randomized clinical trial

Design

The study is a clinical trial (pre-test-post-test) with control group. The sample size (available) is 50 newborns admitted to Al-Zahra Hospital, which are randomly assigned to 25-person intervention and control groups using a table of random numbers. Meanwhile the study is single blind (analyzer) and Phase 2.

Settings and conduct

This study will be performed at NICU in Al-Zahra Hospital in Tabriz. To reduce possible bias, this study will be single blind in which the analyzer will be unaware of the allocation of participants to study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Preterm infants with CLD hospitalized in the NICU; Has received oxygen; At least one parent is present during the bath; Physiological stability at the start of the study; Bathing instructions by a neonatal specialist; The venous line is cut off. Non-inclusion criteria: Having a congenital anomaly; The presence of any kind of wound in the body

Intervention groups

In the intervention group, infants are bathed in the bath at a set time and three times a day, using the protocol of bathing in a bathtub. There is no intervention in the control group, but the need for oxygen and physiological indicators are measured as the intervention group.

Main outcome variables

Oxygen requirements; body temperature; heart rate (HR); respiratory rate (RR).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190326043115N1**

Registration date: **2020-07-06, 1399/04/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-06, 1399/04/16**

Update count: **0**

Registration date

2020-07-06, 1399/04/16

Registrant information

Name

zahra zadmahmoud

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3762 1302

Email address

zadmahmood61@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2020-10-01, 1399/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Swaddling bathing on oxygen needs and physiologic parameters (body temperature, HR and RR) among premature neonates with chronic lung disease (CLD): a randomized clinical trial

Public title

The effect of Swaddling bathing on Oxygen needs in premature neonates with chronic lung disease (CLD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Preterm infants with CLD hospitalized in the NICU (infants in need of oxygen for more than 28 days and reaching a calendar age of 32 to 36 weeks (Postconceptional Age)) Has received oxygen At least one parent is present during the bath Physiological stability at the start of the study (in the last 24 hours there is no decreased saturation, hypothermia, decreased or increased heart rate) Bathing instructions by a neonatal subspecialist The venous line is cut off

Exclusion criteria:

Having a congenital anomaly Any type of wound, including surgical wounds on the skin

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Random numbers table will be used to randomly assign people to study groups. Each participant is assigned a code, and then, by selecting a one-digit refinement on the random number table and moving to a specific side on the number table, the required number of people in each group is determined. The even numbers will be allocated to the intervention group and the odds numbers to the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is planned in such a way that the data analyzer does not know which study group is control or experimental groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

Street address

School of Nursing and Midwifery; South Shariati street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947-977

Approval date

2020-04-20, 1399/02/01

Ethics committee reference number

IR.TBZMED.REC.1399.034

Health conditions studied

1

Description of health condition studied

The need for oxygen in infants with chronic lung disease (CLD).

ICD-10 code

J06

ICD-10 code description

Acute upper respiratory infections of multiple and unspecified sites

Primary outcomes

1

Description

Oxygen needs

Timepoint

It will be measured three times at certain times of the day, every other day, 10 minutes before and 10 minutes and 1 hour after bathing.

Method of measurement

In measuring the need for oxygen, the concentration of saturated oxygen using a blender and the duration of oxygen therapy per day will be measured using a finger oxygen meter that is fixed to the baby's foot.

2

Description

Body temperature

Timepoint

It will be measured three times at certain times of the day, every other day, 10 minutes before and 10 minutes and 1 hour after bathing.

Method of measurement

Using a digital armpit thermometer

3

Description

Heart rate

Timepoint

It will be measured three times at certain times of the day, every other day, 10 minutes before and 10 minutes and 1 hour after bathing.

Method of measurement

Using a finger probe connected to the monitor

4

Description

Respiratory Rate

Timepoint

It will be measured three times at certain times of the day, every other day, 10 minutes before and 10 minutes and 1 hour after bathing.

Method of measurement

By observing and counting chest movements

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, infants are bathed three times, once a day, at a certain time of the day, according to the Swaddle Bathing protocol in the bathtub. Oxygen requirements, body temperature, respiration rate and heart rate will be measured 10 minutes before, 10 minutes and 1 hour after bathing. Room temperature is 26-27 degrees Celsius and water temperature is 38 to 40 degrees Celsius. The bath time is between 6-8 minutes before the baby's feeding time and with the presence, support and participation of at least one parent. The baby's body temperature is fully monitored during the bath to avoid hypothermia and to control stressful symptoms. Bathing will be done using a bathtub, shampoo and other special equipment and in full compliance with the baby's bath protocol as well as hygienic instructions. After bathing, we prepare the baby for nourishment and skin-to-skin contact with the mother.

Category

Treatment - Devices

2

Description

Control group: There is no intervention in the control group, but the amount of oxygen required, body temperature, number of breaths and heart rate 10 minutes before and 10 minutes and 1 hour after bathing as the intervention group (three times, one day in Intermediate will be measured at a set time of day.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and Medical Center; Al-Zahra Hospital; Tabriz University of Medical Sciences

Full name of responsible person

Zahra Zad Mahmoud

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Email

info@alzahrahosp.tbzmed.ac.ir

Web page address

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Hossein Soomi

Street address

Central building of Tabriz University of Medical Sciences; Golgasht street; Azadi street

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Email

research-vice@tbzmed.ac.ir

Web page address

<https://www.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

arshadi9429@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Zad Mahmoud

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

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Full name of responsible person

Zahra Zad Mahmoud

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Arshadi

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University professor

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Ph.D.

Other areas of specialty/work

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Postal code

5138947-977

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Email**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

Information about age, sex, weight, height, multiple children, smoking mother and mother demographic profile.

When the data will become available and for how long

Since 1399

To whom data/document is available

Researchers, doctors and nurses and medical centers

Under which criteria data/document could be used

Research development and improvement in treatment routine

From where data/document is obtainable

Tabriz University of Medical Sciences, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

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

Written request from Tabriz University of Medical

Sciences, Faculty of Nursing and Midwifery, Tabriz
University of Medical Sciences. Visit the center in person

Comments

I do not have