

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comapairing the Weight gaining of Two Groups of Swaddled and not Swaddled Premature Infants Hospitalized in Neonatal Intensive Care Unit

Protocol summary

Summary

This study aimed to determine the effect of swaddling on weight gain in premature infants between 32 to 37 weeks gestational age and weighing 1000 to 2500 g, and aging more than 72 hours, hospitalized in the neonatal intensive care unit. This study is a clinical trial and quasi-experimental study. The sample size for each group is considered 30. Samples will be selected by simple sampling and randomly placed in two groups. According to the study conditions samples will be matched and then placed in order one in case and next in control group. Neonates in case group during 5 days of hospitalization will be swaddled 5 times a day and each time for 30 minutes by researcher with cotton cloth in Frog Flexible way. Samples in control group will receive routine care. The infant will be excluded if his parents at any time and for any reason want so or there is physiological instability. The weigh of neonates in both groups will be measured and recorded in the morning without any clothing and before feeding, by the responsible nurse of each neonate with seca digital scale. The rate of weight gain between two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022726785N1**

Registration date: **2016-05-13, 1395/02/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-13, 1395/02/24

Registrant information

Name

Teni Hatamian Tirkordi

Name of organization / entity

The International Branch of Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 9020

Email address

hatamian.t@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

researcher

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comapairing the Weight gaining of Two Groups of Swaddled and not Swaddled Premature Infants Hospitalized in Neonatal Intensive Care Unit

Public title

The Effect of Swaddling on Weight gaining of Premature Infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Premature infants with gestational age of 32 to 37 weeks; Weight of 1000 to 2500 grams at the start of study; Infant age more than 72 hours; Normal

physiologic parameters; Infants with no severe cardio_respiratory, sepsis, metabolic diseases and any indication for surgery. Exclusion criteria: At any time if parents want to exit their baby from study; Infants who are not stable.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of The International Branch of
Behesti University of Medical Sciences

Street address

No 19, Tavanir Street, Valieasr Street.

City

Tehran

Postal code

Approval date

2016-01-17, 1394/10/27

Ethics committee reference number

IR.SBMU.IASB.REC

Health conditions studied

1

Description of health condition studied

premature infant

ICD-10 code

P07.3

ICD-10 code description

28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed

days) of gestation. Prematurity NOS

Primary outcomes

1

Description

weight

Timepoint

first day of study before intervention and then daily for 5 days

Method of measurement

Seca digital scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: swaddling the infants with cotton cloth, 5 times daily and each time for 30 minutes in 5 continuous days.

Category

Other

2

Description

Control Group: Routine cares in neonatal intensive care unites

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Teni Hatamian Tirkordi

Street address

Mofid Hospital, Shariyati street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Teni Hatamian Tirkordi

Street address

Shahid Beheshti University, Shahid Arabi Street,
Yaman Street, Chamran Highway.

City

Tehran

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 of Shahid Beheshti
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

School of Nursing and Midwifery of Shahid Beheshti
University

Full name of responsible person

Teni Hatamian Tirkordi

Position

MSc student of Critical Care Nursing of Neonates

Other areas of specialty/work

Street address

School of Nursing and Midwifery of Shahid Beheshti
University, Valiasr Street.

City

Tehran

Postal code

Phone

+98 21 8820 2521

Fax

Email

teni_h85@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery of Shahid Beheshti

University

Full name of responsible person

Fatemeh Allai Karahrudi

Position

PHD student/ Faculty

Other areas of specialty/work

Street address

Vasliar street

City

Tehran

Postal code

Phone

+98 21 8846 5140

Fax

Email

falaeeekarahroudy@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School of Nursing and Midwifery of Shahid Beheshti
Medical University

Full name of responsible person

Teni Hatamian Tirkordi

Position

MSc student of neonatal intensive care

Other areas of specialty/work

Street address

Valiasr street

City

tehran

Postal code

Phone

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Fax

Email

teni_h85@yahoo.com

Web page address

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