Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the facilited tucking and free posture on sleep among premature infants hospitalized in neonatal wardstrial

Protocol summary

Summary

The study aimed to investigate the effect of fetal tucking compared to free posture of the body on premature infants sleep, Participants in this study of preterm infants with gestational age of 33-36 weeks and weighting more than 1500 gr admitted to the Al-Zahra medical center in Tabriz. To determine the sample size of the pilot study with 10 infants in each group (four groups) will take. These infant will be randomly assigned into four groups, One day with fetal tucking at right or left lateral position, one day with free posture at right or left lateral position, one day with fetal tucking at supine position and other day with free posture at supine position. Randomized to different states and positions of random permutations ABCD will be used, the infant was observed in four days and Sleep-wake states over a period of 24 hours will be recorded with a video camera. All participants will examine the effect of posture on the amount of sleep, maintaining the posture and position of the infant by four trained nurse will be. The videos recorded will analysis by two observers. Duration of sleep and wakefulness during 24 hours on the sleep Diagram scale will be recorded every five minutes, for the diagnosis of sleep-wake states from the state APIB scale will be used

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407088315N9**
Registration date: **2014-08-12, 1393/05/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-12, 1393/05/21

Registrant information

Name

Leila Valizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-08-01, 1393/05/10

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the facilited tucking and free posture on sleep among premature infants hospitalized in neonatal wardstrial

Public title

the effect of the facilited tucking and free posture on premature infant sleep

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age 33-36 week; post birth age: from 2th day; birth weight more or equal 1500gr; NTISS less 21; No need to respiratory assistance; Do not

have any congenital anomalies; hospitalized in neonatal ward; No contraindication to changes positions; do not SGA and IUGR; do not substance -abusing mother; No single dose of aminophylline and caffeine exclusion criteria: neurologic impairment including convulsion, intraventricular hemorrhage grade 3 or 4; documented congenital infection; Need for surgery; severe medical conditions requiring treatments such as sedatives, muscle relaxants, antiepileptic, aminophylline, or analgesic drug; mother's unwillingness to continue the study; Need to perform various procedures; The use of pacifier; Lumber Puncher at infant

Age
From **2 days** old to **1 month** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size:

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Nursing and Midwifery Faculty, South Shariati Ave

City
Tabriz

Postal code
5138947979

Approval date
2014-07-14, 1393/04/23

Ethics committee reference number
9358

Health conditions studied

1

Description of health condition studied
preterm infant

ICD-10 code
p07.1 - p0

ICD-10 code description
Disorders related to short gestation and low birth weight, not elsewhere classifiedOther low birth weight

Primary outcomes

1

Description
The amount of sleep in 24 hours

Timepoint
Calculate the amount of sleep for 24 hours for each group at the end of each period

Method of measurement
Sleep Diagram scale

Secondary outcomes

1

Description
State development (increasing infant sleep in 24 hour)

Timepoint
Calculate the amount of sleep for 24 hours for each group at the end of each period

Method of measurement
Sleep Diagram scale

Intervention groups

1

Description
One day with fetal tucking at right or left lateral position.The infant was observed in one days and Sleep-wake states over a period of 24 hours will be recorded with a video camera. All participants will examine the effect of posture on the amount of sleep, maintaining the posture and position of the infant by four trained nurse will be.

Category
Treatment - Other

2

Description
One day with free posture at right or left lateral position. The infant was observed in one days and Sleep-wake states over a period of 24 hours will be recorded with a video camera. All participants will examine the effect of posture on the amount of sleep, maintaining the posture and position of the infant by four trained nurse will be.

Category
Treatment - Other

3

Description
One day with fetal tucking at supine position. The infant

was observed in one days and Sleep-wake states over a period of 24 hours will be recorded with a video camera. All participants will examine the effect of posture on the amount of sleep, maintaining the posture and position of the infant by four trained nurse will be.

Category

Treatment - Other

4

Description

One day with free posture at supine position. The infant was observed in one days and Sleep-wake states over a period of 24 hours will be recorded with a video camera. All participants will examine the effect of posture on the amount of sleep, maintaining the posture and position of the infant by four trained nurse will be.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and Therapeutic Center Al-Zahra

Full name of responsible person

Leila Valizadeh

Street address

Al-Zahra Hospital, Bagh Shomal Cross, South Artesh Street, Tabriz

City

Tabriz

2

Recruitment center

Name of recruitment center

Educational and Therapeutic Center Al-Zahra

Full name of responsible person

Leila Valizadeh

Street address

Nursing and Midwifery Faculty, South Shariati Ave -

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Reza Rashidi

Street address

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street

City

Tabriz

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

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

Nursing and Midwifery Faculty

Full name of responsible person

Golnar Ghahremani

Position

Master Science Student of Neonatal Intensive Care

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Professor assistant

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Person responsible for updating data

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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