Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of massage on physiological Parameters of Premature infants under Nasal continuous positive airway pressure through nasal (NCPAP) in Al-Zahra Hospital, Tabriz, 2010.

Protocol summary

Summary

This triple-blind study investigates the effect of massage on physiological responses of premature infants treated with Nasal-CPAP in NICU. A total of 90 premature infants who are eligible will be randomly allocated into the following three groups: control, experimental group 1 (massage with coconut oil) and experimental group 2 (sunflower oil). Massage therapy is done by the researcher (NICU student) with modify Weiss method in accordance with the conditions of newborns and neonatologist order. Then the baby will be massaged with coconut and sunflower oils during the day and every 15 minutes on three consecutive days. The massage starts from the neck and ends on the legs. Neck, back, hands, and legs are massaged but the head, chest, and abdomen are not messaged. Respiratory rate, heart rate, blood pressure, temperature, and oxygen saturation, inhaled oxygen concentration and neonatal complications will be measure five minutes before the procedure and three times during the massage (5, 10, and 15 minutes after the message) and 5 minutes after the massage and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101234613N3**
Registration date: **2011-03-29, 1390/01/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-03-29, 1390/01/09

Registrant information

Name

Sousan Valizadeh Dehkharghani

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

2011-02-14, 1389/11/25

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of massage on physiological Parameters of Premature infants under Nasal continuous positive airway pressure through nasal (NCPAP) in Al-Zahra Hospital, Tabriz, 2010.

Public title

Effect of massage on physiological Parameters of Premature infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age 28-32 weeks and

weight 1000 to 2000 grams, treated with continuous positive airway pressure, not treated by respirator, infants under NCPAP after 12 hours of birth, Axillary temperature is between 36/5-37° C, not having abnormalities or congenital neurological problems, cardiac-vascular and inherited diseases, Arterial blood oxygen saturation at least 92 percent, not having contraindication for touch. Exclusion criteria: mother’s addiction to alcohol, cigarettes or drugs or other medications, any indication for surgery, gastric disorders, intestinal or central nervous system disorders, having a chest tube, infants who require FIO2 more than 70 percent, having serious systemic infection, tachycardia (more than 180 beats per minute), bradycardia (less than 90 beats per minute), resistant (more than two time)

Age
From **28 years** old to **32 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Deputy of Research, Tabriz University of Medical Sciences

Street address
Deputy of Research, Tabriz University of Medical Sciences

City
Tabriz

Postal code
51668-44199

Approval date
2011-01-17, 1389/10/27

Ethics committee reference number
در هشتادو هشتمین جلسه کمیته اخلاق مورخ 89/10/27

Health conditions studied

1

Description of health condition studied
Premature Newborn NCPAP hospitalized in NICU

ICD-10 code
P22.0

ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
physiological Parameters of Premature infants under NCPAP

Timepoint
5 minutes before massage, 5, 10, 15 minutes massage and 5 minutes after massage

Method of measurement
monitor device model S1600 poyandegan rahe saadat, wellshaleene digital and manufactured Medin Easy Blender

Secondary outcomes

empty

Intervention groups

1

Description
In premature infants treated with NCPAP initially Respiratory Rate (RR), heart rate (HR), Fraction of Inspired oxygen (FIO2) and arterial oxygen saturation (SatO2), blood pressure (BP) and body temperature (from axillary) (T) in position Peron determined and is recorded in the checklist. The infants were randomly assigned to three groups: Intervention groups 1(massage with sunflower oil) 10 ml oil per kg birth weight is used. Massage therapy is done by the researcher (NICU student) with modify Weiss method in accordance with the conditions of newborns and neonatologist order. Then the baby's massage with coconut and sunflower oils during the day and once every 15 minutes on three consecutive days is given. Infant massage started of the neck and ends his legs. Neck, back and hands and legs infant massage is given and the head, chest and abdominal massage does not hold the baby. Research fellow in five minutes before the procedure and three times during the massage (5 minutes, 10 and 15) and then after 5 minutes of massage, respiration, heart rate, blood pressure and temperature, and oxygen saturation concentration inhaled oxygen and neonatal complications resulting from the above NCPAP.

Category
Treatment - Drugs

2

Description
Intervention group 2 (massage with coconut oil) 10 ml oil per kg birth weight is used. Massage therapy is done by the researcher (NICU student) with modify Weiss method in accordance with the conditions of newborns and neonatologist order. Then the baby's massage with coconut and sunflower oils during the day and once every 15 minutes on three consecutive days is given. Infant massage started of the neck and ends his legs. Neck, back and hands and legs infant massage is given and the head, chest and abdominal massage does not hold the baby. Research fellow in five minutes before the procedure and three times during the massage (5 minutes, 10 and 15) and then after 5 minutes of massage, respiration rate, heart rate, blood pressure and temperature, and oxygen saturation concentration and neonatal complications resulting from the above NCPAP.

Category
Treatment - Drugs

3

Description
Control group (routine care without massage) also were measured respiration rate, heart rate, blood pressure and temperature, and oxygen saturation concentration in the same time.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person
Najmeh Ajoodaniyan

Street address
Al-Zahra Hospital, Artesh Hospital, Baghshmal Crossroads, Tabriz

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Deputy, Tabriz University of Medical Sciences

Full name of responsible person
Dr Sousan Valizadeh

Street address
Pediatric Department of Nursing and Midwify Faculty

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research Deputy, 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Najmeh Ajoodaniyan

Position
Nursing Master of Science Student neonatal intensive care

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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