

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The Effect of Skin Massage on Physiologic Parameters and Outcomes in Preterm Infants

Protocol summary

Summary

This study was conducted to evaluate the effect of massage on physiological parameters in premature infants in the age group of 28-32 weeks. 135 premature infants who had study criteria's (gestational age between 28-32 weeks; birth weight between 1000-1500 gram; Apgar score above 7 at 5 minutes) were divided into 3 groups by using simple random method. The first group involved infants who were massaged with olive oil during 10 days and 3 times, 15 minutes per day by their mother. The second group of infants was also above method without the use of massage oil. And the third group of infants did not receive any intervention. During these 10 days, researchers recorded all information such as infant's physiologic parameters and infant's weight daily. Infant weight gain is considered as the primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107036918N2**

Registration date: **2011-10-19, 1390/07/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-19, 1390/07/27

Registrant information

Name

Alehe Seyedrasooli

Name of organization / entity

Faculty of Nursing & Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 0365

Email address

seyedrasooly@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy for research, Tabriz University of Medical Sciences

Expected recruitment start date

2010-12-17, 1389/09/26

Expected recruitment end date

2011-03-16, 1389/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Skin Massage on Physiologic Parameters and Outcomes in Preterm Infants

Public title

Effect of Massage

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age infant between 28-32 weeks; Birth weight between 1500 - 1000 gr ; No anomaly, No congenital and systemic disease; No history of mechanical ventilation; No Maternal alcohol, tobacco or drugs ; Apgar score above 7 at 5 minutes; Physiological status of the infant is stabilized (not apnea and is not bradycardia). ; There are no medical contraindications of massage Exclusion criteria: Now the bad baby; Fever in infants; Lack of mother cooperation to continue; No fill the time of study

Age

To 4 years old
Gender
Both
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: 135
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

1
Registry name
Central Is Not Registered in Any
Secondary trial Id
No Id
Registration date
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Medical Sciences University of Tabriz
Street address
Deputy of Medical Sciences University of Tabriz
City
Tabriz
Postal code
977-5138947
Approval date
2009-09-28, 1388/07/06
Ethics committee reference number
5147/4/5

Health conditions studied

1
Description of health condition studied
Massage
ICD-10 code
Z00-Z99
ICD-10 code description
Health supervision and care of other healthy infant and child

Primary outcomes

1
Description
Weight
Timepoint
Every Day for 10 Days
Method of measurement
Balance

Secondary outcomes

1
Description
Nosocomial Infection
Timepoint
End of 10 Days
Method of measurement
Blood Cultures

Intervention groups

1
Description
The first group of babies who were three times daily for 10 days and 15 minutes by a mother who had been trained in massage techniques, massage using olive oil.
Category
Prevention

2
Description
Babies in the second group were also three times daily for 10 days and 15 minutes without the use of massage oils.
Category
Prevention

3
Description
Infants in control group received the usual care and did not receive any intervention .
Category
Diagnosis

Recruitment centers

1
Recruitment center
Name of recruitment center
Alzahra Educational Center Affiliated Medical Sciences of Tabriz;Iran
Full name of responsible person
Rukiye salimi
Street address
Bagshomal Square;Tabriz;Iran

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

دانشگاه علوم پزشکی

Full name of responsible person

Deputy of Tabriz University of Medical Sciences

Street address

Dr. Reshidi

City

Tabriz University of Medical Sciences

Grant name

Grant code / Reference number

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

Yes

Title of funding source

دانشگاه علوم پزشکی

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

Faculty of Nursing & Midwifery

Full name of responsible person

Mahnaz Jabreili

Position

MS

Other areas of specialty/work

Street address

Shariety South St; Faculty of Nursing & Midwifery ;

Tabriz ; Iran

City

Tabriz

Postal code

34751745

Phone

+98 41 1477 2699

Fax

Email

jabreilim@yahoo.com

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