Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

seyyedrasooly@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
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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