Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparative study of the Effect of massage therapy with sweet almond oil and sesame oil on weight gain of premature neonates

Protocol summary

Summary

The present study is a clinical randomized unblinded trial with the aim of investigating the effect of Massage therapy with sesame and sweet almond oils on weight gain of premature infants. The trial includes 60 infants hospitalized at the neonatal intensive care unit of Shohadaye Kargar and Shahid Sadoughi hospitals. The inclusion criteria are Iranian nationality, fetal age of 30-35 weeks, breast or dried milk feeding and a stable medical condition. The exclusion criteria includes Sepsis, convulsion, fetal disorders, dermal infection, congenital cardiac or digestive diseases, disease of nervous system, respiratory distress, surgery, Parenteral nutrition and starving at the time of intervention, parental discontent, discharge of the newborn before the intervention and sensitivity to almond and sesame oils. The subjects will be assigned to massage therapy with either sesame or almond oil or the control group using random numbers table. Tools used for the sampling included demographic questionnaire and beurer scale. The infants in the experimental group will be tested for sensitivity to the oils on the day before the start of the intervention. Massaging will be performed from day 7 through 14 postpartum, 2 times a day for at least 10 minutes at one hour after each feeding. Initially, the subject will be placed in prone position and massaged at the back head, neck, loin and the extremities for 5 minutes followed by the massaging of the face, neck, chest, abdomen and the extremities at the supine position. The control group will receive routine cares.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072511230N3**
Registration date: **2017-02-23, 1395/12/05**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-02-23, 1395/12/05

Registrant information

Name
Zahra Pourmovahed
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shahid Sadoughi Yazd University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative study of the Effect of massage therapy with sweet almond oil and sesame oil on weight gain of premature neonates

Public title

Effect of massage with oil on weight gain of premature neonates

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Iranian nationality, fetal age of 30-35 weeks, breast or dried milk feeding and a stable medical condition. Exclusion criteria: Sepsis, convulsion, fetal disorders, dermal infection, congenital cardiac or digestive diseases, disease of nervous system, respiratory distress, surgery, Parenteral nutrition and starving at the time of intervention, parental discontent, discharge of the newborn before the intervention, and sensitivity to almond and sesame oils.
Age
From **7 months** old to **8 months** old
Gender
Both

Phase
N/A
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

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Sadoughi Yazd University of Medical Sciences
Street address
Shahid Sadoughi Yazd University of Medical Sciences organizaftion, shahid Dr. bahonar squre,Yazd
City
Yazd
Postal code
8916978477
Approval date
2016-05-29, 1395/03/09
Ethics committee reference number
IR.SSU.REC.1395.29

Health conditions studied

1

Description of health condition studied
weight
ICD-10 code
R63.5
ICD-10 code description
Abnormal weight gain

Primary outcomes

1

Description
weight
Timepoint
at 8 am on the seventh day and fourteenth after birth
Method of measurement
beurer weighing scale

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Massaging will be performed from day 7 through 14 postpartum, 2 times a day for at least 10 minutes at one hour after each feeding. Initially, the subject will be placed in prone position and massaged at the back head, neck, loin and the extremities for 5 minutes followed by the massaging of the face, neck, chest, abdomen and the extremities at the supine position. almond oil(manufactured by kimiadarou Sepehr company)
Category
Other

2

Description
Massaging will be performed from day 7 through 14 postpartum, 2 times a day for at least 10 minutes at one hour after each feeding. Initially, the subject will be placed in prone position and massaged at the back head, neck, loin and the extremities for 5 minutes followed by the massaging of the face, neck, chest, abdomen and the extremities at the supine position. sesame oil(manufactured by barij essence pharmaceutical company)
Category
Other

3

Description
The control group will receive routine cares.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital and Shohadaye Kargar
Full name of responsible person
Maryam Dabirifard
Street address
Faculty of Nursing and Midwifery, SafaiehStreet, Yazd
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shahid SadoughiYazd University of Medical Sciences
Full name of responsible person
Vice chancellor for research of Shahid Sadoughi Yazd University of Medical Sciences
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Faculty of Nursing and Midwifery, Safaieh Street, Yazd
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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 SadoughiYazd 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
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Shahid Sadoughi Yazd University of Medical Sciences
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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