

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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

Country

Iran (Islamic Republic of)

Phone

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Email address

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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 squire, 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, Safaieh Street, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

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

Street address

Faculty of Nursing and Midwifery, Safaieh Street, Yazd

City

Yazd

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 Sadoughi Yazd 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

Shahid Sadoughi Yazd University of Medical Sciences

Full name of responsible person

Zahra pourmovahed

Position

Master of Nursing, PhD research student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Web page address

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