

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of massage therapy with and without oil on weight gain and triglyceride levels of premature

Protocol summary

Study aim

Comparison of the effect of massage therapy with and without oil on weight gain and triglyceride levels in premature

Design

Double blind, parallel group randomized-controlled clinical trial with 94 cases are divided into 2 intervention groups, massage therapy with oil (33 cases), massage therapy without oil (30 cases) and control group (30 cases).

Settings and conduct

In this double blind, randomized-controlled clinical trial , which is done to evaluate the effect of massage therapy with and without oil on weight gain and triglyceride levels of 94 preterm infants admitted to the neonatal intensive care unit at Shohada Tajrish and Mahdiah Hospital, Tehran, Iran, according to the inclusion and exclusion criteria, are divided into three groups. After filling the permission form with parents, care giver divides the neonates according to the random numbers and random numbers generator software into three groups and parents are not aware of the type of intervention. The massage therapists were informed about groups' division, while the nurse who measured the daily weight and serum triglyceride samples, the researcher who recorded the information, and the statistician who analyzed the data were blind to grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Neonates with gestational age less than 37 weeks. Hemodynamically stable condition and without serious medical illness and receiving at least 60 kcal per day orally. Exclusion criteria: Hemodynamically unstable

Intervention groups

The first intervention group: oil massage therapy. Second intervention group: massage therapy without oil. Control group: routine neonatal care without any intervention.

Main outcome variables

Weigh; Serum triglyceride level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180610040036N3**

Registration date: **2022-07-12, 1401/04/21**

Registration timing: **retrospective**

Last update: **2022-07-12, 1401/04/21**

Update count: **0**

Registration date

2022-07-12, 1401/04/21

Registrant information

Name

Narges Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4442 7956

Email address

nargesgholami@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-01, 1398/06/10

Expected recruitment end date

2021-04-30, 1400/02/10

Actual recruitment start date

2019-09-01, 1398/06/10

Actual recruitment end date

2021-04-30, 1400/02/10

Trial completion date

2021-04-30, 1400/02/10

Scientific title

The effect of massage therapy with and without oil on weight gain and triglyceride levels of premature

Public title

Massage therapy in premature weigh gain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age less than 37 weeks At least 60 kcal / kg intake daily orally Not having any serious medical condition

Exclusion criteria:

Hemodynamically unstable

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **94**

Actual sample size reached: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

First, a framework was made of numbers 1-94 , then the assignment of these numbers to group 1-3 was determined based on the random numbers table. A computer software program (www.random.org) was used to produce random numbers to allocate neonate to 3 groups and were be placed in an envelope and marked with neonate number and group code (massage therapy with oil, massage therapy without oil and control).

Blinding (investigator's opinion)

Double blinded

Blinding description

After filling the permission form with parents, care giver divides the neonates according to the random numbers and random numbers generator software into three groups and parents are not aware of the type of intervention.The massage therapists were informed about groups' division, while the nurse who measured the daily weight and serum triglyceride samples, the researcher who recorded the information, and the statistician who analyzed the data were blind to grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti university of medical sciences

Street address

Kodakyar st , Shahriary Sq , Chamran High way

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2019-08-27, 1398/06/05

Ethics committee reference number

IR.SBMU.MSP.REC.1398. 550

Health conditions studied

1

Description of health condition studied

Premature weight and serum triglyceride level

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

weight

Timepoint

Before the intervention and five-day period of study

Method of measurement

Rossmax WE300 baby digital scale

Secondary outcomes

1

Description

Serum triglyceride level

Timepoint

Before intervention and fifth day of study

Method of measurement

mg per decilitre (Automated Analyzer, Mindray BS-200 analyzer)

Intervention groups

1

Description

First intervention group: massage therapy with oil. The massage therapist performed 15-minute massage with coconut oil daily for 5 days at 9 AM and 13 PM o'clock.

Category

Treatment - Other

2

Description

Second intervention group: massage therapy without oil. The massage therapist performed 15-minute massage with tepid water daily for 5 days at 9 AM and 13 PM o'clock.

Category

Treatment - Other

3

Description

Control group: Routine neonatal care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish and Mahdiah Hospital

Full name of responsible person

Ali Naseh

Street address

Qods Sq, Tajrish street

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Tehran

Province

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989934148

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pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak

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1985717434

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Narges Gholami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Final data has been given to Vice-Chancellor of Research Affairs of Shahid Beheshti University of Medical Sciences

When the data will become available and for how long

2022-2031

To whom data/document is available

pediatricians

Under which criteria data/document could be used

All researchers are allowed to receive data details and protocols according professional ethics.

From where data/document is obtainable

Contact with authors

What processes are involved for a request to access data/document

By email to author(nargesgholami@sbmu.ac.ir). It takes about 7 days.

Comments