

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of Massage Therapy With or Without Physical Exercises on the weight gain of Premature Infants.

Protocol summary

Study aim

Study Effect Of Massage Therapy With Or Without Exercises on The Weight Gain premature Hospitalized In pediatric Ward .

Design

Intervention Study ,control Group,Randomise

Settings and conduct

This Study performed on 45 low birth weight neonates hospitalized in pediatric ward of Shohada Hospital divided 3 Groups. each Groups consist 15 infants. Massage Group received Massage with Olives oil twice a day for 15 minutes in 5 days. (after Feeding). and Massage and exercises groups in Addition of massage were done in form of extension and flexion for 5 minutes. the Massage and Exercises was done By Reasercher. infants weight was measured and Recorded By a Assistant Reasercher with constant of Measuring scale before intervention and Fifth Day (the end of intervention).

Participants/Inclusion and exclusion criteria

Birth weight lower than 2500grams, gest/age 30 to 36 weeks

Intervention groups

3 Groups consist control group, Massage group and Massage and exercises group

Main outcome variables

Birth weight; gestational Age and weight before study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170520034039N3**

Registration date: **2018-05-18, 1397/02/28**

Registration timing: **retrospective**

Last update: **2018-05-18, 1397/02/28**

Update count: **0**

Registration date

2018-05-18, 1397/02/28

Registrant information

Name

Rokhsareh Barati

Name of organization / entity

Shiraz university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 917 169 9948

Email address

barati_r@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-10-13, 1395/07/22

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

2016-10-13, 1395/07/22

Actual recruitment end date

2017-02-19, 1395/12/01

Trial completion date

empty

Scientific title

Comparison of the Effect of Massage Therapy With or Without Physical Exercises on the weight gain of Premature Infants.

Public title

Study Effect of Massage Therapy With or Without Physical Exercises on the weight gain Premature Infants.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Too Agreement Of Parentes Gestational Age 30-36
Weeks Lake of Evidence for Congenital Disorder Birth
Weight Lower Than 2500 gram Breast Feeding Iranian
Nationality Age Above 1 week

Exclusion criteria:

Congenital Disorder

Age

From **7 days** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Qualify Infants divided in to three groups of massage, massage by exercises and control group with random number tables(Permutation block).researcher formed different Permutations.(a:Massage),(b:Massage with exercises)and (c:control).then for selection to put the her finger from a site from number tabels to column and row. she write down related permutation when observed number1-9.

Blinding (investigator's opinion)

Single blinded

Blinding description

Infants weight was measured and recorded by a recorder who didnt know anything about group divisions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Shiraz University of Medical Sciences

Street address

Zand Ave, Medical Scince Centra Buldg

City

Shiraz

Province

Fars

Postal code

71345-1978

Approval date

2016-07-20, 1395/04/30

Ethics committee reference number

IR.sums.rec.1395.86

Health conditions studied

1

Description of health condition studied

low birth weight

ICD-10 code

p07

ICD-10 code description

Disorders of newborn related to short gestation and low birth weight, not elsewhere classified

Primary outcomes

1

Description

infant weight

Timepoint

Before intervention and end of study

Method of measurement

By spificic scale

Secondary outcomes

empty

Intervention groups

1

Description

Massage Group recived Massage by olives oil (sufra, yellowish) after breakfast and lunch for 15 minutes for consecutive days,by a researcher .

Category

N/A

2

Description

Massage and exercises group (2)in addition of massage ,exercises stimulation were done in form of extension and flexion for 5 minutes

Category

N/A

3

Description

Control group ricived any intervention .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada Hospital Of Bandare Lengeh
Full name of responsible person
Rokhsareh Barati
Street address
Shohada Hospital,Hosein Abad Ave.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The university of shiraz
Full name of responsible person
Dr Seyed Baser Hashemi
Street address
Zand street, Shiraz
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Province
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Fax
Email
verdp@sums.ac.ir
Grant name
95-7673
Grant code / Reference number
ir.sums.Rec.1395.86
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The university of shiraz
Proportion provided by this source
80
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

2

Sponsor

Name of organization / entity
The Unevercity of Shiraz
Full name of responsible person
Dr Seyed Baser Hashemi
Street address
Zand street ,Shiraz
City
Shiraz
Province
Fars
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Email
verdep@sums.ac.ir
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Proportion provided by this source
80
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
The University of Shiraz,
Full name of responsible person
Edraki Mitra
Position
Instructor of Department
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Bachelor
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71936-13119
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Fax
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barati_r@sums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

part of data

When the data will become available and for how long

8 month after publish

To whom data/document is available

Reaserchers

Under which criteria data/document could be used

Request to shiraz university of medical scinces

From where data/document is obtainable

rokhsareh .barati (barati.rokhsareh@gmail.com)

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

call for me and tell me his goal.

Comments