

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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 befor intervention and Fifth Day (the end of intervention).

##### Participants/Inclusion and exclusion criteria

Birth weight lower than 2500grams,gest/age30 to 36 weeks

##### Intervention groups

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

##### Main outcome variables

Birth weight;gestational Age and weight befor 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.  
**City**  
Bandar Lengeh  
**Province**  
Hormozgan  
**Postal code**  
79781  
**Phone**  
+98 76 4422 2421  
**Email**  
rokhsareh@barati.com

## 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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Shiraz  
**Province**  
Fars  
**Postal code**  
713451978  
**Phone**  
+98 71 1235 7282  
**Fax**  
**Email**  
verdp@sums.ac.ir  
**Grant name**  
95-7673  
**Grant code / Reference number**  
ir.sum.s.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  
**Postal code**  
713451978  
**Phone**  
+98 71 1235 7282  
**Fax**  
**Email**  
verdep@sums.ac.ir  
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**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  
**Street address**  
Namazi Ave., Shiraz  
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edrakim@sums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
The Uneversity of Shiraz  
**Full name of responsible person**  
Montasere Sedighe  
**Position**  
instructor of pediatriac department  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
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College of Nursing and Midwifery Shiraz  
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Montaseris@sums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
The Uneversity of Shiraz  
**Full name of responsible person**  
Rokhsareh Barati  
**Position**  
Student of Master of Neonatology Nursing

**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Shiraz ,Nursing College  
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Shiraz  
**Province**  
Fars  
**Postal code**  
71936-13119  
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+98 76 4422 2421  
**Fax**  
**Email**  
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