

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of efficacy of body massage alone and sunflower oil massage on growth parameters of low birth weight neonates:

Protocol summary

Summary

In a randomized clinical trial , LBW preterm neonates whom were admitted to NICU of Shahid Sadoughi Hospital , Yazd, Iran , were evaluated. The neonates were randomly distributed into three groups to receive standard routine care , moderate pressure body massage or massage with sunflower oil , three times in a day for consecutive 14 days by their mothers. These neonates were followed up and growth parameters (weight , height and head circumference) of all neonates were measured 14 days after starting of intervention , at ages of one month and two months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100411007N1**
Registration date: **2012-10-22, 1391/08/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-10-22, 1391/08/01

Registrant information

Name

Sedighah Akhavan Karbasi

Name of organization / entity

Shahid Sadoughi Medical Sciences University,
Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 4000

Email address

sakarbasi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd,
Iran

Expected recruitment start date

2010-10-24, 1389/08/02

Expected recruitment end date

2011-03-22, 1390/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of body massage alone and sunflower oil massage on growth parameters of low birth weight neonates:

Public title

Body massage alone and sunflower oil massage on growth parameters of low birth weight neonates:

Purpose

Supportive

Inclusion/Exclusion criteria

Eligible participants included newborns who had gestational age 33- 37 weeks ,birth weight of 1500-1999 grams , were without birth asphyxia and hypoxic ischemic insults, aged less than ten days , were medically stable and did not need any drug therapy , were stayed in the hospital for at least 5 days after enrollment of intervention. Multiple pregnancies , sepsis and meningitis , infants with major congenital malformations , small for gestational age (SGA), chromosomal abnormalities , genetic syndromes and neonates who had serious complications such as intraventricular hemorrhage, severe bronchopulmonary dysplasia and necrotizing enterocolitis during NICU

admission period were excluded .

Age

To **1 year** 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)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences

Street address

Bahonar Square, Central Building

City

Yazd

Postal code

Approval date

2010-10-21, 1389/07/29

Ethics committee reference number

7680

Health conditions studied

1

Description of health condition studied

Low birth weight

ICD-10 code

P07.1

ICD-10 code description

other low birth weight

Primary outcomes

1

Description

Weight

Timepoint

at 14 days after intervention, at ages of one month and two months

Method of measurement

clinical exam

2

Description

Height

Timepoint

at 14 days after intervention, at ages of one month and two months

Method of measurement

clinical exam

3

Description

Head circumference

Timepoint

at 14 days after intervention, at ages of one month and two months

Method of measurement

clinical exam

Secondary outcomes

1

Description

side effects

Timepoint

During 14 days of intervention

Method of measurement

clinical exam

Intervention groups

1

Description

standard and routine care of neonate

Category

Treatment - Other

2

Description

moderate pressure body massage three times in a day for consecutive 14 days by their mothers

Category

Treatment - Other

3

Description

moderate pressure body massage with sunflower oil , three times in a day for consecutive 14 days by their mothers

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU of Shahid Sadoughi Hospital

Full name of responsible person

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences , Yazd , Iran

Full name of responsible person

Sedighah Akhavan Karbasi MD

Street address

Shahid Sadoughi Hospital

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences , Yazd , Iran

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 University of Medical Sciences , Yazd , Iran

Full name of responsible person

Sedighah Akhavan Karbasi MD

Position

Associate professor

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital

City

Yazd

Postal code

Phone

+98 35 1822 4000

Fax

Email

sakarbasi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences , Yazd , Iran

Full name of responsible person

Sedighah Akhavan Karbasi MD

Position

Associate professor

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital

City

Yazd

Postal code

Phone

+98 35 1822 4000

Fax

Email

sakarbasi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences , Yazd , Iran

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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