

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of massage versus no massage on weight gain in low birth weight neonates: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of massage versus no massage on weight gain in low birth weight neonates.
Design: a double blinded randomized clinical trial.
Setting and conduct: The eligible neonates who are admitted in NICU of Fatemieh Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** (a) birth weight less than 2400 gr; (b) gestational age between 25 to 34 weeks; (c) stability of the clinical condition of the neonate based on the neonatologist decision; (d) beginning of breastfeeding. **Exclusion criteria:** (a) age of lower than 5 days; (b) presence of genetic disorder, congenital cardiomyopathy, central nerves system disorder, intra-ventricular hemorrhage; (c) history of maternal drug abuse. **Intervention:** massage for 15 min three times a day for 5 days including reciprocating touch of the top area of the head to the neck, from neck to shoulders, shoulder to hand, back to waist, thigh to ankle in a prone position and then flexion and extension movements of the arms and legs in the supine position. **Control:** inpatient neonates without massage. **Primary outcome:** (a) measuring weight daily for 5 days using the meter; (b) measuring height daily for 5 days using weight scale; (c) measuring head circumference daily for 5 days using the meter.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411189014N47**
Registration date: **2014-11-30, 1393/09/09**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-11-30, 1393/09/09

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of massage versus no massage on weight gain in
low birth weight neonates: a double blinded randomized
clinical trial

Public title

Effect of massage versus no massage on weight gain in
low birth weight neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) birth weight less than 2400 gr; (b)

gestational age between 25 to 34 weeks; (c) stability of the clinical condition of the neonate based on the neonatologist decision; (d) beginning of breastfeeding. Exclusion criteria: (a) age of lower than 5 days; (b) presence of genetic disorder, congenital cardiomyopathy, central nerves system disorder, intra-ventricular hemorrhage; (c) history of maternal drug abuse.

Age

From **5 days** old to **28 days** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization: random assignment of the neonates schematically one at a time to intervention and control groups. Blinding: Babies do not have sufficient understanding and have no effect on the outcomes of interest. In addition, the examiner who will examine the neonates is another person that will not be aware of the type of intervention. Therefore, the trial will be run as double blinded.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2014-10-16, 1393/07/24

Ethics committee reference number

P/16/35/9/3456

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**

measuring weight

Timepoint

daily for 5 days

Method of measurement

using the meter

2**Description**

measuring height

Timepoint

daily for 5 days

Method of measurement

using weight scale

3**Description**

measuring head circumference

Timepoint

daily for 5 days

Method of measurement

using the meter

Secondary outcomes**1****Description**

nothing

Timepoint

nothing

Method of measurement

nothing

Intervention groups**1****Description**

inpatient neonates without massage

Category

Other

2

Description

: massage for 15 min three times a day for 5 days including reciprocating touch of the top area of the head to the neck, from neck to shoulders, shoulder to hand, back to waist, thigh to ankle in a prone position and then flexion and extension movements of the arms and legs in the supine position.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Sahar Johari

Street address

Fatemieh Hospital, Pasdaran Ave

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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 the Technology, Hamadan
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

Department of Speech Therapy, School of
Rehabilitation Sciences, Hamadan University of
Medical Scien

Full name of responsible person

Sahar Johari

Position

Speech therapists

Other areas of specialty/work

Street address

Department of Speech Therapy, School of
Rehabilitation Sciences, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Phone

+98 81 3838 0572

Fax

Email

saharjohari85@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Speech Therapy, School of
Rehabilitation Sciences, Hamadan University of
Medical Scien

Full name of responsible person

Mostafa Daemi

Position

Speech therapists

Other areas of specialty/work

Street address

Department of Speech Therapy, School of
Rehabilitation Sciences, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Phone

+98 81 3838 0572

Fax

Email

daemist@yahoo.com

Web page address

Person responsible for updating data

Contact

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