

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of massage on weight gain in very low birth weight neonates

Protocol summary

Summary

This study aimed to evaluate the effect of massage on weight gain in very low birth weight neonates. Inclusion criteria include birth weight between 1000-1500 gr; appropriate weight for gestational age; oral milk feeding and no parenteral nutrition dependency; no substance abuse by mother during pregnancy; infant without congenital diseases or disorder in central nervous system. Exclusion criteria: respiratory distress and receive oxygen support; gastrointestinal disorder such as vomiting or milk intolerance; photo therapy and TORCH syndrome. 40 neonates with 1000-1500 gr birth weight are selected according to inclusion and exclusion criteria by non-random sampling and will randomly be assigned to two groups as control and intervention, 20 member in each group. Study period is from 20.3.2012 until 20.2.2015. The control group will receive usual care for premature newborns. The intervention group will receive massage therapy for one week, three times per day, duration of each time was 15 min, at least 4 hrs. interval. They will treated by the researcher under the supervision of physiotherapist. At the start and the end of study information about growth monitoring include (weight, high and head circumference) will be measured. Primary outcome: weight bearing after one week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092019232N1**
Registration date: **2014-12-09, 1393/09/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-09, 1393/09/18

Registrant information

Name

Fahimeh Kazemian Baboli

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Non Communicable Diseases in Children Research Center, Babol University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of massage on weight gain in very low birth weight neonates

Public title

Effect of massage on newborn weight gain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: birth weight 1000 - 1500 gr; appropriate for gestational age; breast feeding and no need for parenteral nutrition; physical stability; lake of maternal drug abuse in pregnancy; infants without congenital anomalies and CNS disorders; permit professor of infants and consent of the parents Exclusion

criteria: respiratory distress and receive oxygen support;
GI problems such as vomiting and milk intolerance;
infant that need surgery; photo therapy and blood
transplantation; TORCH syndrome

Age

From **7 years** old to **1 month** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic committee of Babol University of Medical
Sciences

Street address

Babol University of Medical Sciences, Keshavarz
Street, Babol

City

Babol

Postal code

47976-47745

Approval date

2013-10-12, 1392/07/20

Ethics committee reference number

9236622

Health conditions studied**1****Description of health condition studied**

low birth weight newborn

ICD-10 code

P07.14

ICD-10 code description

Other low birth weight newborn, 1000-1249 gr

2**Description of health condition studied**

Low birth weight newborn

ICD-10 code

P07.15

ICD-10 code description

Other low birth weight newborn, 1250-1499 gr

Primary outcomes**1****Description**

weight

Timepoint

At baseline and at the end of the first week

Method of measurement

with balance

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

Height

Timepoint

At baseline and at the end of the first week

Method of measurement

With Meter

2**Description**

Head circumference

Timepoint

At baseline and at the end of the first week

Method of measurement

With meter

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

Usual care for premature newborns. at the end of study
growth monitoring will be done for them.

Category

Treatment - Other

2**Description**

Massage therapy sessions will be done 15 minutes long
fourth daily for one week. All sessions will be done with
researcher under supervision of physiotherapist. at the
end of study growth monitoring will be done for them.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rohani Hospital

Full name of responsible person

Fahimeh Kazemian Baboli

Street address

Ayatollah Rohani Hospital, Ganjafrooz Street, Babol, Mazandaran, Iran

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Moghadamnia

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City

Babol

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 of Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Fahimeh Kazemian Baboli

Position

Nurse

Other areas of specialty/work**Street address**

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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