

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The impact of abdominal massage on infant feeding in very low birth weight admitted in the Neonatal Intensive Care Unit (NICU)

Protocol summary

Study aim

Feeding tolerance

Design

Performing a massage with the "I love u" technique is three times a day for five consecutive days in the massage group and to perform standard care in the control group. the recorder is not aware of the control and massage group

Settings and conduct

Performing "I Love U" massage Technique at 8 am , 2 pm and 8 p.m For 15 minutes from the day 6 , the weight measured at 8 am daily,insert oral feeding 6Fr Size, messure of the residual volume of stomach lower than 25 % -50 % of previous nutrition with a 5 ml syringe and a slow aspiration in two times, before the massage and before the meal began , messure abdominal circumference before any massage,begin feeding to 5 - 10 ml/kg/day every 4 to 6 hours and if tolerance feeding occurred, increase meal 140-160ml/kg/day 8 times per day and every3hours. evaluate vomiting and record frequency of defecation

Participants/Inclusion and exclusion criteria

Very low birth weight neonates.Inclusion criteria:the feed of their intestine through the oral tube is also the birth weight of lower than 1500 .Exclusion criteria: abnormal cardiac and digestive system , hypoxic damage , respiratory failure and respiratory support , Necrotizing Entero Colitis (NEC) suspected and Gastroesophageal Reflux (GER) and lavage.

Intervention groups

Group 1 : In the massage group 28 infant receive massage therapy in three times for five consecutive days , group 2: in the control group 28 infants receive standard care.

Main outcome variables

Lavage before and after massage therapy -messure weigh gain and abdominal circonfrence - measurement frequency vomiting and dification

General information

Reason for update

Acronym

MT

IRCT registration information

IRCT registration number: **IRCT20180103038205N1**

Registration date: **2018-01-12, 1396/10/22**

Registration timing: **retrospective**

Last update: **2018-01-12, 1396/10/22**

Update count: **0**

Registration date

2018-01-12, 1396/10/22

Registrant information

Name

Mohsen Haghshenas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8301

Email address

m.haghshenas@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

2016-11-21, 1395/09/01

Actual recruitment end date

2017-11-22, 1396/09/01

Trial completion date

empty

Scientific title

The impact of abdominal massage on infant feeding in very low birth weight admitted in the Neonatal Intensive Care Unit (NICU)

Public title

Massage and feeding tolerance

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

The feed of their intestine through the oral tube is also the birth weight of lower than 1500 g without intestine obstract, abdomen surgery, NEC, contraindication of massage

Exclusion criteria:

Abnormal cardiac and digestive system , hypoxic damage , respiratory failure and respiratory support , NEC suspected and GER and lavage

Age

From **189 days** old to **231 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **40**

In the checklist compiled by the researcher every three hours and during five consecutive days , data related to each sample were recorded

Actual sample size reached: **58**

More than 1 sample in each individual

Actual sample size in each individual: **40**

In the checklist compiled by the researcher every three hours and during five consecutive days , data related to each sample were recorded

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The recorder is not aware of the control and massage group

Placebo

Used

Assignment

Single

Other design features

Intervention for five consecutive days

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق پزشکی علوم پزشکی بابل

Street address

خیابان گنج افروز، دانشگاه علوم پزشکی بابل

City

Babol

Province

Mazandaran

Postal code

45745-47176

Approval date

2016-11-09, 1395/08/19

Ethics committee reference number

MUBABOL.HRI.REC.1395.52

Health conditions studied

1

Description of health condition studied

The impact of the massage on daily weight gain and decrease gastric residual volume and distention and duration of hospital stay and the number of vomiting of VLBW infant compared to control group that has not received massage.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

massage therapy

Timepoint

every 3 hours (from 8 a.m. to 5 a.m.next day)

Method of measurement

Observing and recording

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention Group: ' I Love U ' massage Technique at 8 am , 2 pm and 8 p.m For 15 minutes from the day 6 , the weight measure at 8 am daily, insert oral feeding 6Fr Size,measure of the residual volume of stomach lower than 25 % -50 % of previous nutrition with a 5 mm syringe and a slow aspiration in two times, before the massage and before the meal began,measure abdominal circumference before any massage,begin feeding to 5 - 10 ml/kg/day every 4 to 6

hours and if tolerance feeding increase meal 140-160ml/kg/day 8 promises per day and every 3 hours. evaluate vomiting, record frequency of defecation.

Category

Treatment - Other

2**Description**

Control group: Gather information like the intervention group and receive routine care. recorder does not know the control and massage group.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rouhani hospital

Full name of responsible person

Mohsen Haghshenas

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Babol university Of medical sciences, University square, Babol

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

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**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Hamed

Position

nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Mohsen Haghshenas

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Province

Mazandaran

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available