

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of emollient therapy with olive oil on weight gain in very low birth weight neonates

Protocol summary

Summary

The purpose of this study is to investigate the effect of olive oil rubbing on weight gain in very low birth weight neonates. forty-six neonates will be selected with convenience sampling and they will be assigned based on time of birth alternatively in two groups of intervention (n=23) and control (n=23). the first neonate only will be assigned in control or intervention group randomly. Inclusion criteria such as birth weight between 1000 and 1500 g, physiological stability, age at least 10 days, breast milk 120 cc/kg, parent consent. Exclusion criteria include: need for respiratory support, photo therapy, congenital anomalies, sepsis and skin disease. Intervention group will be lubricated with 3 cc olive oil at 3 times daily by nurses. Neonates of each group will be weighted by digital balance at a specified hour every day until 10 days. The difference of daily weight from first day of study until 10 days between infants in the two groups will be compared at end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121319232N2**

Registration date: **2015-01-22, 1393/11/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-22, 1393/11/02

Registrant information

Name

Fahimeh Kazemian Baboli

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3538 2160

Email address

f.kazemian@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Babol University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of emollient therapy with olive oil on weight gain in very low birth weight neonates

Public title

The effect of emollient therapy with olive oil on weight gain in very low birth weight neonates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: birth weight between 1000 and 1500 g; physiological stability; age at least 10 days; breast milk 120 cc/kg; parent consent. Exclusion criteria: need for respiratory support; photo therapy; congenital anomalies; sepsis and skin disease.

Age

From **10 days** old to **20 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 46

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

2014-10-14, 1393/07/22

Ethics committee reference number

933868

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 baseline until 10th day

Method of measurement

balance

Secondary outcomes

1

Description

height

Timepoint

At baseline and end of study

Method of measurement

with meter

2

Description

head circumference

Timepoint

At baseline and end of study

Method of measurement

meter

Intervention groups

1

Description

control group receive routine care only.

Category

Other

2

Description

Intervention group will be lubricated 3 times a day with 3 cc olive oil by nurses.

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

Ganj afrooz street, University Square

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 Kazamian Baboli

Position

Master science nursing of NICU

Other areas of specialty/work

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Position

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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