

# 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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

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**Other areas of specialty/work**

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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*