

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The effect of oropharyngeal mother's milk until the beginning of oral feeding in preterm infants on nutritional outcomes

#### Protocol summary

##### Study aim

The effect of oral-pharyngeal breastfeeding until the onset of oral feeding in premature infants on nutritional outcomes

##### Design

Excel software rand function was used to randomize a clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 80 infants.

##### Settings and conduct

Infants of 30-25 weeks were admitted to the NICU of Amir Al-Momenin Hospital in Semnan. Each infant will be randomly assigned to the breast milk group or placebo in a ratio of 1: 1. Using aseptic techniques, one researcher prepares insulin syringes with 0.1 ml of sterile BM or distilled water. The syringes are covered with a matte coating to prevent them from becoming blind. The baby's name is placed on the syringe, and a separate box is placed to store the milk syringes of each baby in the refrigerator and maintain the box blindness for the babies in the control group. Each infant will receive 0.2 ml of BM or sterile distilled water every 2 hours until the start of oral feeding, regardless of intestinal milk intake. At each turn, the contents of a syringe are poured to the right of the oral cavity. After 30 s, the contents of the second syringe are poured to the left.

##### Participants/Inclusion and exclusion criteria

Infants with a gestational age of 25-30 weeks and infants with congenital malformations of the gastrointestinal tract, urinary, renal systems or need a ventilator, a history of substance abuse or HIV infection in the mother, and mothers who are not breastfed are excluded.

##### Intervention groups

Starting 48 to 72 hours after the birth of each baby, every two hours, warm each syringe for 5 minutes in the incubator and then pour the contents of one syringe to the right of the oral cavity and after 30 s, pour the contents of the second syringe to the left.

##### Main outcome variables

Lavage, time of discharge from hospital, the onset of intestinal feeding, and oral feeding.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220509054798N1**

Registration date: **2022-05-21, 1401/02/31**

Registration timing: **prospective**

Last update: **2022-05-21, 1401/02/31**

Update count: **0**

##### Registration date

2022-05-21, 1401/02/31

##### Registrant information

##### Name

Fatemeh Kelich

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3330 1998

##### Email address

fatemehkelich1990@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-22, 1401/04/01

##### Expected recruitment end date

2023-01-21, 1401/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of oropharyngeal mother's milk until the beginning of oral feeding in preterm infants on nutritional outcomes

**Public title**

The effect of oropharyngeal mother's milk until the beginning of oral feeding in preterm infants on nutritional outcomes

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Gestational age 25 to 30 weeks

**Exclusion criteria:**

Requires a ventilator Having a congenital disease

Substance abuse by the infant's mother The mother of the infant is infected with HIV

**Age**

From **1 day** old to **2 months** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Computer-generated randomization will hide from all physicians, physicians, nurses, parents, and placebo and breastfeeding physicians.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Insulin syringes will be used to administer breast milk.

One researcher then uses aseptic techniques to prepare insulin syringes with 0.1 ml of sterile breast milk or distilled water. It then labels the syringes and seals them with a matte finish to prevent them from becoming blind. The baby's name is then written on the syringe again.

There will be a separate box for each baby to store milk syringes inside the refrigerator shelf and a box for babies in the control group for syringes containing distilled water to be blinded.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

In other studies, only colostrum was used for a limited time, and its effects on safety issues were investigated. In contrast, breast milk was used in this study and

continued until oral feeding.

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

**Street address**

Unit 2, Jahan complex, Hakim Elahi 60 street, Hakim Elahi Blvd, Semsnan, Semnan.

**City**

Semnan

**Province**

Semnan

**Postal code**

3515611979

**Approval date**

2022-02-02, 1400/11/13

**Ethics committee reference number**

IR.MUBABOL.REC.1400.281

**Health conditions studied**

1

**Description of health condition studied**

Nutritional tolerance in premature infants

**ICD-10 code****ICD-10 code description****Primary outcomes**

1

**Description**

Nutritional tolerance

**Timepoint**

Every two hours

**Method of measurement**

Residual gastric volume

**Secondary outcomes**

1

**Description**

Time to start intestinal feeding

**Timepoint**

The day of feeding by gavage

**Method of measurement**

day

## Intervention groups

1

### Description

Intervention group: Administration of breast milk at the rate of 0.2 ml every 2 hours by the oropharyngeal method

### Category

Other

2

### Description

Control group: Administration of 0.2 ml sterile distilled water every 2 hours by oropharyngeal method

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Amir Al-Momenin Hospital

#### Full name of responsible person

Fatemeh Kelich

#### Street address

Amir Al-Momenin Hospital, No. 9771, Shahid Mostafa Khomeini Blvd., Imam Hossein Square, Semnan.

#### City

Semnan

#### Province

Semnan

#### Postal code

3519734731

#### Phone

+98 23 3346 0066

#### Email

amir.hospital@semums.ac.ir

#### Web page address

<https://amirhos.semums.ac.ir/>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Dr. Hossein Najafzadeh Varzi

#### Street address

Unit 02, Jahan complex, Hakim Elahi 60 street, Hakim Elahi boulevard, Semnan, Semnan

#### City

Semnan

#### Province

Semnan

#### Postal code

35188257678

#### Phone

+98 23 3330 1998

#### Email

fatemehkelich1990@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### 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

Babol University of Medical Sciences

#### Full name of responsible person

Fatemeh Kelich

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

Unit 02, Jahan complex, Hakim Elahi 60 street, Hakim Elahi boulevard, Semnan, Semnan

#### City

Semnan

#### Province

Semnan

#### Postal code

35188257678

#### Phone

+98 23 3330 1998

#### Email

fatemehkelich1990@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Seyedeh Roghayeh Jafarian Amiri

#### Position

Assistant Professor

#### Latest degree

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Mazandaran, Babol, Ganj Afrooz St., Babol University of Medical Sciences

**City**

Babol

**Province**

Mazandaran

**Postal code**

۴۷۱۷۶-۴۷۷۴۵

**Phone**

۰۱۱-۳۲۱۹۹۵۹۲-۵

**Email**

jafarianamiri@gmail.com

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

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh Kelich

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Unit 02, Jahan complex, Hakim Elahi 60 street, Hakim Elahi boulevard, Semnan, Semnan

**City**

Semnan

**Province**

Semnan

**Postal code**

۳۵۱۸۸۲۵۷۶۷۸

**Phone**

+98 23 3330 1998

**Email**

fatemehkelich1990@gmail.com

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

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

**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**

Undecided - It is not yet known if there will be 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