

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparision of early and late human milk fortification on growth ,osteopenia and feeding tolerance in preterm newborns in shariati hospital from 2012- 2013.

#### Protocol summary

##### Summary

The aim of the study was to investigate Comparision of early and late human milk fortification on growth ,osteopenia and feeding tolerance in preterm newborns in shariati hospital from 2012- 2013. that Inclusion criteria: All pretem infants 28-34 weeks. Exclusion criteria: major congenital anomaly; emergency surjery (PDA ROP,...); infant hospitalize less 7 days ,infant transfer to other care system . This study includes 80 cases that divided on 2 groups of 40 infants 28-34 weeks thus during the study period was 6 weeks, birth weight ,height and head circumfrence, admision weight,Around the abdomen, bowel sounds, gastric lavage.NEC symptoms such as drowsiness, lethargy, biliary lavage, lavage more than 50% milk three hours, increased around abdominal of more than 2cm and stability than the previous feeding period of 6-4 hours and a clear blood in the stool as NEC onset of symptoms and NEC clinical and radiographic signs of disease are reviewed. Another group in the same group are considered as two sides Blind. At the end of the study the rate of weight, height and head circumfrence gain in 4 weeks age,serum calsum,serum phosphor,serum Alkalin phosphatase and serum vitamin -D measure in 6 weeks ago not and two groups are compared

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201301239568N4**  
Registration date: **2013-12-20, 1392/09/29**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-12-20, 1392/09/29

##### Registrant information

###### Name

Golnaz Rezaeizadeh

###### Name of organization / entity

Maternal Fetal Neonatal Research Center,Tehran  
University of Medical Sciences, Tehran, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6119 2357

###### Email address

mfnhrc@tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2012-03-20, 1391/01/01

##### Expected recruitment end date

2013-03-21, 1392/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparision of early and late human milk fortification on growth ,osteopenia and feeding tolerance in preterm newborns in shariati hospital from 2012- 2013.

##### Public title

Comparision of early and late human milk fortification on growth ,osteopenia and feeding tolerance in preterm newborns in shariati hospital from 2012- 2013.

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: All preterm infants 28-34 weeks

Exclusion criteria: infants less 28 weeks and more 34 week; major congenital anomaly; emergency surgery (PDA ROP,...); infant hospitalized less 7 days; infant transfer to other care system

## Age

From **28 years** old to **34 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Comparison of early and late human milk fortification on growth, osteopenia and feeding tolerance in preterm newborns in shariati hospital from 2012- 2013.

## Secondary IDs

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Ethics committee of Tehran University of Medical Sciences, 6 th floor of Tehran University of Medical Sciences, ghods St., Keshavarz blv, Tehran, Iran

##### City

Tehran

##### Postal code

14197

#### Approval date

2013-09-24, 1392/07/02

#### Ethics committee reference number

91-4-10-19451-94587

## Health conditions studied

### 1

#### Description of health condition studied

weight gain

#### ICD-10 code

R62.8

#### ICD-10 code description

failure to weight gain

## Primary outcomes

### 1

#### Description

Weight gain of infants

#### Timepoint

at birth, pre intervention and 4 weeks ago

#### Method of measurement

with digital scale

### 2

#### Description

osteopenia

#### Timepoint

6weeks ago

#### Method of measurement

serum calcium, serum phosphorus, serum Alkaline phosphatase and serum vitamin -D measure

### 3

#### Description

po intolerance

#### Timepoint

Daily during the intervention

#### Method of measurement

Around the abdomen, bowel sounds, gastric lavage, fecal occult blood and full of feces

## Secondary outcomes

### 1

#### Description

sepsis

#### Timepoint

Daily during the intervention

#### Method of measurement

physical exam and laboratory

### 2

#### Description

NEC

#### Timepoint

Daily during the intervention

#### Method of measurement

physical exam, laboratory, radiography

## Intervention groups

## 1

### Description

Intervention group: using fortifier, which is 3.6 gram sachet for 25 cc mother milk .

### Category

Prevention

## 2

### Description

Control group: preterm infant late human milk fortification from 50-100 cc/kg feeding

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shariati Hospital

#### Full name of responsible person

Dr Negar Sajjadian

#### Street address

Shariati Hospital , north kargar blv, Tehran, Iran

#### City

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences/breast feeding research

#### Full name of responsible person

Dr Mamc Shariat

#### Street address

Vaiasr hospital, Imam Khomeini Hospital complex, Keshavarz blv, Tehran, Iran

#### City

Tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Tehran University of Medical Sciences/breast feeding research

### 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

Tehran University of Medical Sciences

#### Full name of responsible person

Dr Marzieh Asgharyan

#### Position

Resident of Pediatric

#### Other areas of specialty/work

#### Street address

Bahrami Hospital, Kiaie blv, Tehran, Iran

#### City

Tehran

#### Postal code

#### Phone

+98 21 7757 3797

#### Fax

#### Email

asgharyan\_m@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr Paymane Alizade

#### Position

Assistant Professor Of Neonatology /Daneshyar

#### Other areas of specialty/work

#### Street address

Bahrami Hospital, Kiaie blv, Tehran, Iran

#### City

Tehran

#### Postal code

00982122782896

#### Phone

+98 21 2278 2896

#### Fax

#### Email

p.alizadet@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr Marzieh Asgharyan

#### Position

Resident of Pediatric

#### Other areas of specialty/work

#### Street address

Bahrami Hospital, Kiaie blv, Tehran, Iran

#### City

Tehran

**Postal code**

00982177573797

**Phone**

+98 21 7757 3797

**Fax**

**Email**

asgharyan\_m@yahoo.com

**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*