

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

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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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