

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparing outcomes of different feeding volume in preterm infants

Protocol summary

Summary

In this controlled randomized clinical trial, 140 preterm infants are enrolled in Tabriz Alzahra Hospital in a 6 month period of time. They will be randomly assigned in three groups; feeding of milk advanced at 20 ml/kg/day (group one, 60 neonates), feeding of milk advanced at 24 ml/kg/day (group two, 40 neonates), and feeding of milk advanced at 30 ml/kg/day (group three, 40 neonates). Main study outcome is "Process of determining weight gain in premature infants" and "hospitalization days" is the study secondary outcome. Outcomes will be compared between the three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904284417N1**

Registration date: **2011-06-12, 1390/03/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-12, 1390/03/22

Registrant information

Name

Fazileh Bashar Hashemi

Name of organization / entity

Tabriz medical university

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 0062

Email address

fhashemi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2010-10-07, 1389/07/15

Expected recruitment end date

2011-04-04, 1390/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing outcomes of different feeding volume in preterm infants

Public title

Comparing outcomes of different feeding volume in preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age (30-34wk), birth weight (1000-2000 gr) , Exclusion criteria: congenital anomalous, gastrointestinal obstruction, septicemia, intraventricular hemorrhage grade 3 and more, congenital heart disease.

Age

To **1** year old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

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**

Tabriz University of Medical Sciences Ethics Committee

Street address

Golgashat Avenue, Kamarbandi Street

City

Tabriz

Postal code**Approval date**

2009-10-03, 1388/07/11

Ethics committee reference number

5/4/4894

Health conditions studied**1****Description of health condition studied**

Feeding premature infants

ICD-10 code

p07

ICD-10 code description

Disorders related to short gestation and low birth weight, not elsewhere classified

Primary outcomes**1****Description**

Process of determining weight gain in premature infants

Timepoint

1 to 2 weeks

Method of measurement

Scale

Secondary outcomes**1****Description**

Hospitalization duration

Timepoint

1 to 2 weeks

Method of measurement

Day

Intervention groups**1****Description**

Intervention group 1: Milk volume of 20 ml/kg/day in 60 preterm infants

Category

Other

2**Description**

Intervention group 2: Milk volume of 24 ml/kg/day in 60 preterm infants

Category

Other

3**Description**

Intervention group 3: Milk volume of 30 ml/kg/day in 60 preterm infants

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Fazileh Bashar Hashemi

Street address

No 132, Atebba Alley, Emam Street

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostad Rahimi

Street address

Golgashat Avenue, Kamarbandi Street

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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

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Fax**Email**

fazileh.hashemi@gmail.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Fazileh Bashar Hashemi

Position

PhD - Neonatologist

Other areas of specialty/work**Street address**

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Science

Full name of responsible person

Fazileh Bashar Hashemi

Position

PhD - Head of neonatology ward

Other areas of specialty/work**Street address**

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Tabriz University of Medical Science

Full name of responsible person

Fazileh Bashar Hashemi

Position

PhD - Neonatologist

Other areas of specialty/work**Street 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