

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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

Golgasht 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

Golgasht 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***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**

No 132, Atebba Alley, Emam Street

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**Phone**

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**Fax****Email**

fazileh.hashemi@gmail.com

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

Tabriz University of Medical Science

**Full name of responsible person**

Fazileh Bashar Hashemi

**Position**

PhD - Neonatologist

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

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**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*