

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The comparison early outcomes intermittent gavage in preterm infants :randomized clinical trial

Protocol summary

Summary

Premature infants are unable to coordinate sucking,swallowing and breathing, therefore require gavage feeding.intermittent gavage can be given by gravity or push.gravity feed is defined as an intermittent when milk is poured into a syringe(using the syringe as a funnel) that is attached to an intra-gastric feeding tubeand milk is allowed to drip into the infants stomach by gravity and adjutant height.push is administered using a syringe to push milk into the infants stomach.objective this study is :comparison early outcomes intermittent gavage in preterm infants.study infants are inrolled with sixth and seventh day of birth,infants have the same nasal tube feeding and received human milk.infant position before and half hour after gavage is supine.outcomes in this study consist of :physiological index(heart rate,breathing,O2sat) before ,execution time and 10 minute after gavage in one day(8-12 times) .feeding tolerance is assessed by:gastric residual volume(GVR,determined by aspiration of gastric contents from the indwelling nasal tube feeding every 2-3hour in all infants),emesis,abdominal distention and necrotizing enterocolits for two days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408205168N7**
Registration date: **2015-03-15, 1393/12/24**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-03-15, 1393/12/24

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Science

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-06-20, 1394/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison early outcomes intermittent gavage in preterm infants :randomized clinical trial

Public title

The comparison early outcomes intermittent gavage in preterm infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:1- gestational age(28-34)week and AGA 2-NG tub feeding in sixth and seventh day 3- weight<2500gr 4- absence of major congenital malformation and heart disease 5- did not have any apnoea and shock in 24 hour 6-Disruption

ventilation,NCPAP,HFNC 7-parents satisfaction 8-high apgar(fifth minutes apgar was more seven) 9- without umbilical vein catheter. Exclusion criteria:1- affection to PDA to need medical 2-NEC in execution time 3-sepsis 4- IVH(2 degree and more) 5-inexistence stability vital sign 6-lack of parents satisfaction 7-hypotention need to vasopresor

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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

Street address

Central Building of Tabriz University of Medical Sciences,Golgasht Avenue, azadi street,Tabriz

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33359680

Approval date

2015-02-23, 1393/12/04

Ethics committee reference number

93180

Health conditions studied

1

Description of health condition studied

Infant gavage outcome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Physiological index(heart rate,breathing and O2 saturation

Timepoint

Before ,execution time and 10 minutes after gavage in one day

Method of measurement

Before,execution time and 10 minutes after gavage written in check list

Secondary outcomes

1

Description

Gastric residual volume is secondary outcome,emesis,abdominal distention and necrotizing enterocolitis for two days checking instance side effect

Timepoint

Before feeding gavage every 2-3 hours in two days gastric residual checking and side effect recording in check list

Method of measurement

Aspiration of gastric contents from the indwelling nasal tube feeding every 2-3 hours and emesis with observation and abdominal distention and NEC with physician diagnosis

Intervention groups

1

Description

Infant gavage with gravity in intervention group

Category

Prevention

2

Description

Infant gavage with administered using a syringe in control group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Educational Center Affiliated

Full name of responsible person

Samaneh Sadat Sajassi

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South artesh Avenue-across from Baghshomal

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Science

Full name of responsible person

Malihe Assadollahi

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Department of Pediatrics, School of nursing and Midwifery, Tabriz

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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 Science

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

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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