

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of non-nutritive sucking on survival gastric residual volume in preterm newborn: A randomized controlled clinical trial

Protocol summary

Summary

The aim of this A randomized controlled clinical trial is to evaluate the effects of non-nutritive sucking on the survival gastric residual volume of gavages in preterm infants. In this study 86 infants with inclusion criteria: (age between 28-32 weeks ; weight between 750-1500 gm; clinically stable ;no medical contraindications for non-nutritive sucking, No congenital abnormalities and digestive system problems) and the baby will excluded from the study if occurs problems such as : Intraventricular hemorrhage grade 3 and 4 , Periventricular locomalacy , necrotizing enterocolitis , BPD , chronic diseases of the lung, mechanical ventilation , neonatal seizure , positive culture , meningitis , NPO baby for any reason, more than 24 hours. All infants will be randomly selected and divided into two groups. For infants who are in the first group, non-nutritive sucking with pacifier will begin since the beginning of gavages (during gavages) and will continue for 10 minutes after its (the method of gavages will be pushed in all neonates). This practice, three times a day (in the afternoon in hours 3, 5 and 7) will continue for 7 days. Infants in the second group will be gavages on routine ward's program but they will not be received non-nutritive sucking. In both groups, after initiation of feeding, amount of gastric residual volume, as the primary outcome will be measured at 1 and 2 hours by a syringe during study days and recorded in the relative forms then compared by researcher. It is not possible to blind study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601264613N16**

Registration date: **2016-03-03, 1394/12/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-03, 1394/12/13

Registrant information

Name

Sousan Valizadeh Dehkharghani

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

009804134751706- 34796770

Email address

valizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-02-29, 1394/12/10

Expected recruitment end date

2016-05-30, 1395/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of non-nutritive sucking on survival gastric residual volume in preterm newborn: A randomized controlled clinical trial

Public title

Effects of non-nutritive sucking on survival gastric residual volume in preterm newborn

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Infants' age between 28-32 weeks; weight between 750-1500 gm; clinically stable infants Physiological indicators including heart rate , respiratory rate and O2 sat) No medical contraindications for non-nutritive sucking, No congenital abnormalities and digestive system problems by verifying the doctor ordered for gavage feeding, breastfeeding, not the Ventilator Exclusion criteria :If, after entering the study , problems such as : Intraventricular hemorrhage grade 3 and 4 , Periventricular locomalacy , necrotizing enterocolitis , BPD , chronic diseases of the lung, mechanical ventilation , neonatal seizure , positive culture , meningitis , NPO baby for any reason, more than 24 hours the baby will excluded from the study.

AgeTo **1 month** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **86****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Deputy of Research, Tabriz University of Medical Sciences ,Golgasht street , Tabriz Tabriz East Azerbaijan Iran, Islamic Republic Of 5138947-977

City

Tabriz

Postal code

5138947-977

Approval date

2016-01-18, 1394/10/28

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

prematurity

ICD-10 code

Z76.2

ICD-10 code description

Health supervision and care of other healthy infant and child

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

Gastric residual volume

Timepoint

One and two hours after gavage

Method of measurement

Using a syringe

Secondary outcomes

empty

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

Intervention group 1: Infants who are in this group,non-nutritive sucking with pacifier will begin since the beginning of gavages (during gavages) and will continue for 10 minutes after its (the method of gavages will be pushed in all neonates). This practice, three times a day (in the afternoon in hours 3, 5 and 7) will continue for 7 days.

Category

N/A

2**Description**

Control group : Infants who are in this group will be gavages on routine ward's program but they will not be received non-nutritive sucking.

Category

Treatment - Other

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

Al-Zahra Hospital

Full name of responsible person

poor ashoori - sheryzad

Street address

Educational and Therapeutic Center Al-Zahra ,
Baghshmal Crossroads, Artesh Street, Tabriz

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2**Recruitment center****Name of recruitment center**

29 Bahman hospital

Full name of responsible person

Tagizadeh-zahra

Street address

Tabriz-29 Brahman boulevard

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

Vice chancellor for Research of Tabriz University of
Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

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Deputy of Research and Technology, Tabriz University
of Medical Sciences ,Golgashst street , Tabriz, East
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Tabriz

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

Yes

Title of funding source

Vice chancellor for Research of 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**

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Full name of responsible person

Tahereh Rafiezadeh

Position

Student of Master degree in Neonatal Intensive Care
Nursing

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

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

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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