

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of short-term consequences of calcium bolus administration with continuous infusion in intravenous feeding of preterm infants

Protocol summary

Study aim

Comparison of short-term consequences of calcium bolus administration with continuous infusion in intravenous feeding of preterm infants

Design

In this Clinical Trial, 90 patients will be enrolled and randomly divided into two parallel 45-patient-group.

Settings and conduct

This study will be performed on premature infants with gestational age less than 32 weeks or birth weight less than 1500 grams who are hospitalized in the intensive care unit of Al-Zahra Hospital in Tabriz and undergo total parenteral nutrition (TPN). For this purpose, patients will be examined in 2021. Two methods of intravenous calcium administration will be examined and compared. Serum alkaline phosphatase, 25 (OH) D3, and serum PTH will also be measured in the first week and one month or when TPN is stopped. These tests will be repeated for all patients at 45 days of age and will be evaluated for premature neonatal osteopenia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all premature infants under 32 weeks or less weighing 1500 g are fed intravenously through the central vein. Exclusion criteria: severe asphyxia; chromosomal abnormalities or congenital metabolic disorders; maternal history of hyperparathyroidism or vitamin D disorders

Intervention groups

In the first group, calcium will be administered as a solution of calcium gluconate through intravenous bolus intravenously. In the second group, calcium gluconate will be mixed in intravenous feeding serum and will be administered as a 24-hour infusion. In the group treated with 24-hour infusion, 10% calcium gluconate solution at a dose of 4-5 mL/kg/day will be added to intravenous feeding serum.

Main outcome variables

Blood levels of alkaline phosphatase; calcium; PTH, and vitamin D

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210913052466N1**

Registration date: **2022-01-02, 1400/10/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-02, 1400/10/12**

Update count: **0**

Registration date

2022-01-02, 1400/10/12

Registrant information

Name

Asmar Amirasalanazadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-08, 1400/06/17

Expected recruitment end date

2022-09-08, 1401/06/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of short-term consequences of calcium bolus administration with continuous infusion in intravenous feeding of preterm infants		Ethics committee of Tabriz University of Medical Sciences	
Public title		Street address	
Comparison of short-term consequences of calcium bolus administration with continuous infusion in intravenous feeding of preterm infants		Third Floor, Central Building of Tabriz University of Medical Sciences, Golgasht Street	
Purpose		City	
Treatment		Tabriz	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		East Azarbaijan	
All premature infants under 32 weeks or less of 1,500 gr who are fed intravenously through the central vein.		Postal code	
Exclusion criteria:		5165665931	
Severe asphyxia Chromosomal abnormalities or congenital metabolic disorders Maternal history of hyperparathyroidism or vitamin D disorders		Approval date	
Age		2021-08-29, 1400/06/07	
To 1 month old		Ethics committee reference number	
Gender		IR.TBZMED.REC.1400.501	
Both		Health conditions studied	
Phase		1	
2		Description of health condition studied	
Groups that have been masked		Premature infants	
- Participant - Outcome assessor - Data analyser		ICD-10 code	
Sample size		E83.9	
Target sample size: 90		ICD-10 code description	
Randomization (investigator's opinion)		Disorder of mineral metabolism, unspecified	
Randomized		Primary outcomes	
Randomization description		1	
Patients will be randomly assigned to intervention and control groups based on permissive block design. First, a single-digit random number will be generated if the chosen number is 0 to 4 AB permutation will be used and if it is between 5 and 9 BA permutation will be used. This method will be employed to complete the sample size.		Description	
Blinding (investigator's opinion)		Prematurity osteopenia	
Double blinded		Timepoint	
Blinding description		First week and 4 to 6 weeks after bith	
Patients who enter the study and assessing physicians and also statistical analyzers have no information about the grouping of infants admitted to the NICU.		Method of measurement	
Placebo		Calcium, P, ALP will be done by spectrophotometric method with autoanalyzer and vitamin D level will be checked by ELISA method and finally the level of PTH will be measured by quantitative luminescence method with automatic Immulight.	
Not used		Secondary outcomes	
Assignment		1	
Parallel		Description	
Other design features		Side effects of intravenous calcium injection: bradycardia, arrhythmia, seizures, skin necrosis, subcutaneous calcium	
Secondary Ids		Timepoint	
empty		All side effects are evaluated instantly by the medical staff	
Ethics committees		Method of measurement	
1		Observation	
Ethics committee		Intervention groups	
Name of ethics committee		1	
		Description	

Intravenous administration of 10% calcium gluconate with a dose of 1 mg/kg of body weight for 3 to 4 times daily from second day of birth till 34 week post menstrual age to intervention group

Category

Treatment - Drugs

2

Description

24-hour infusion, 10% solution of calcium gluconate with a dose of 4-5 mL/kg /day into intravenous feeding serum from second day of birth till 34 week post menstrual age to intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Hospital of Tabriz

Full name of responsible person

Asmar Amir Arsalan Zadeh

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East Azerbaijan Province, Tabriz, Shishgelan St, Children's HospitalC

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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Tabriz university of medical sciences, Golgasht street, Azadi avenue

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<https://researchvice.tbzmed.ac.ir/>

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Majid Mahallei

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Second floor, Central Building, Golgasht St, Tabriz

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available