Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Amirasalanzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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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

Public title
Comparison of short-term consequences of calcium bolus administration with continuous infusion in intravenous feeding of preterm infants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All premature infants under 32 weeks or less of 1,500 gr who 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
Age
To **1 month** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
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.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients who enter the study and assessing physicians and also statistical analyzers have no information about the grouping of infants admitted to the NICU.
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
Third Floor, Central Building of Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2021-08-29, 1400/06/07
Ethics committee reference number
IR.TBZMED.REC.1400.501

Health conditions studied

1

Description of health condition studied
Premature infants
ICD-10 code
E83.9
ICD-10 code description
Disorder of mineral metabolism, unspecified

Primary outcomes

1

Description
Prematurity osteopenia
Timepoint
First week and 4 to 6 weeks after bith
Method of measurement
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.

Secondary outcomes

1

Description
Side effects of intravenous calcium injection: bradycardia, arrhythmia, seizures, skin necrosis, subcutaneous calcium
Timepoint
All side effects are evaluated instantly by the medical staff
Method of measurement
Observation

Intervention groups

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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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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Web page address

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

Assisstant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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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