

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Calcitriol and Cholecalciferol on biochemical markers of Metabolic Bone Disease in very low birth weight infants

Protocol summary

Study aim

Comparison of Calcitriol and Cholecalciferol on biochemical markers of Metabolic Bone Disease in very low birth weight infants .

Design

Randomized Control Trials ,Double blind

Settings and conduct

This study will be in a setting of Neonatal Intensive Care Unit of Alzahra teaching hospital of Tabriz. After receiving of parental consent 72 VIBW Infants recruited . After receiving to full feed level(120 cc/kg/d of Breast milk) they are randomly divided in two groups: Control group receives 400 IU/day 25 hydroxy vitamin D3 (cholecalciferol) n=35) and study group receives 0.2 µg/kg/day Calcitriol (n= 37) . Biochemical markers will be checked as baseline ,after 3 and 6 weeks of treatment and before discharge.

Participants/Inclusion and exclusion criteria

inclusion factors: Very low birth weight infants (<1500 gr) born in Alzahra teaching hospital infants whose parent has signed satisfaction factor infants after aging 2 weeks that can tolerate (120cc/kg/day) of breast milk or breast milk with formula exclusion factors: infants with major malformation infants with congenital cardiac disease infants with familial bone disease background infants receiving corticosteroids

Intervention groups

Group 1(control) receives calcitriol 0.2 µg/kg/day and group 2 (study)receives cholecalciferol 400 IU/day . Drugs are calculated to cc and pooled in a insulin syringe. Infants will receive calcitriol or cholecalciferol during feeding with breast milk through NG tube. Supplementation will be continued till discharge

Main outcome variables

biochemical markers of metabolic bone disease including ALP, VitD3 , P ,Ca , PTH and tubular reabsorption of phosphate(TRP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N28**

Registration date: **2018-06-10, 1397/03/20**

Registration timing: **retrospective**

Last update: **2018-06-10, 1397/03/20**

Update count: **0**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2018-05-22, 1397/03/01

Trial completion date

empty

Scientific title

Comparison of Calcitriol and Cholecalciferol on biochemical markers of Metabolic Bone Disease in very low birth weight infants

Public title

Evaluation of effect of different type of vitamin D on biochemical markers of osteopenia of Prematurity

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Inborn Very low birth weight infants (<1500g) in Alzahra Teaching hospital Taking consent of parents Tolerating 120cc/kg/day breast milk or breast milk with formula (Full feed)

Exclusion criteria:

Infants with major malformation Infants with congenital cardiac disease Infants with familial history of bone disease Infants receiving corticosteroids Infants born from mothers with renal failure

Age

From **14 days** old to **28 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **4**

Blood sampling and urine

Actual sample size reached: **72**

More than 1 sample in each individual

Actual sample size in each individual: **4**

Blood sampling and urine

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be by systematic randomization methods and by random numbers made by computer

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients randomly divided in two groups . One group receive Cholecalciferol (VitD3) 400 IU/Day and the other Calcitriol (Rocaltrol) 0.2 µg/kg/day. Before and after 3 and 6 weeks after starting the treatments and before discharge lab data including :ALP , P , Ca ,TRP ,Serum VitD3,PTH will be checked .Data will be collected by a research nurse who is blind to the groups of the infants. Data will be analyzed by a statistician who will be blind to the groups .

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

Research and Technology Deputy of tabriz medical university ,golgasht street,Tabriz

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Tabriz

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East Azarbaijan

Postal code

5166614766

Approval date

2017-12-27, 1396/10/06

Ethics committee reference number

IR.TBZEDMED.REC.1395.1035

Health conditions studied**1****Description of health condition studied**

metabolic bone disease in very low birth weight infants

ICD-10 code

E55.0

ICD-10 code description

decreased bone mineral content relative to the expected level of mineralization seen in conjunction with biochemical and/or radiographic changes

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

Biochemical markers of Osteopenia Prematurity including :ALP , P , Ca

Timepoint

Biochemical marker measurement at baseline , 3 and 6 weeks later starting treatment and before discharge

Method of measurement

Rochas.Anzimatic method by Selectra auto analyzer

2**Description**

serum Vit D3 Level

Timepoint

At baseline , 3 and 6 weeks later after treatment and before discharge

Method of measurement

Electrochemiluminescence method by Alexis

3

Description

Serum parathormon level

Timepoint

Biochemical marker measurement at baseline , 3 and 6 weeks later after treatment and before discharge

Method of measurement

serum level of parathormon hormon is measured with electrochemiluminescence method by Alexis Rochas.

Secondary outcomes

1

Description

Calculation of Tubular reabsorption of phosphate

Timepoint

At the binning of the study , 3 ,6 weeks after treatment and before discharge

Method of measurement

$TRP = 1 - (\text{Urine phosphate} \times \text{Pcreatinine} / \text{Pphosphate} \times \text{U creatinine})$

Intervention groups

1

Description

Intervention group: calcitriol group receives calcitriol 0.2 µg/kg/day (From calcitriol pearl's content pooled in insulin syringe). Infants receives calcitriol during feeding with breast milk through NG tube. Supplementation will continue untill discharge.

Category

Treatment - Drugs

2

Description

Control group:cholecalciferol group receives cholecalciferol 400 IU/day (cholecalciferol's drops pooled in insulin syringe). Infants receives calcitriol with milk through NG tube. Supplementation will continue till discharge

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Teaching hospital of Tabriz

Full name of responsible person

Mohammadbagher Hosseini MD

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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 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

Taher entezar maleki

Position

Associated Professor of clinical pharmacy

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available