Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 receives400 IU/day 25 hydroxy vitamin D3 (cholecalciferol) n=35) and study group receives0.2 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 who their 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 received 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 reabsorbtion 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
Iran (Islamic Republic of)
Phone
+98 21 6695 4709
Email address
tentezarimaleki@razi.tums.ac.ir

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 Cholecaciferol (VitD3) 400 IU/Day and the other Caliteriol (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
Reasearch and Technology Deputy of tabriz medical university ,golgasht street,Tabriz

City
Tabriz

Province
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-(Urine phosphate x Pcreatinine/ Pphosphate x 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
Street address
South Artesh street ,Alzahra Teaching hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5138663134
Phone
+98 41 3553 9162
Fax
+98 41 3556 6449
Email
hosseini.neo@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghacem Joiban Phd
Street address
Golgasht Street ,Tabriz Universit Campous
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3335 7310
Fax
+98 41 3334 4280
Email
ajouyban@hotmail.com
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
Street address
Pharmacy faculty of tabriz medical university,Golgasht street,Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3337 2250
Fax
+98 41 3334 4798
Email
Deanpharmacy@tbzmed.ac.ir

Person responsible for scientific 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
Street address
Pharmacy faculty of tabriz medical university ,Golgasht street,Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
51666414766
Phone
+98 41 3337 2250
Fax
+98 41 3334 4798
Email
tentezari@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Nafiseh Hosseini
Position
student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Pharmacy faculty of tabriz medical university ,Golgasht street,Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166414766
Phone
+98 41 3337 2250
Fax
+98 41 3334 4798
Email
nafisehhosseyni@gmail.com

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