Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of oral calcitriol pulse therapy with oral daily calcitriol method in hemodiyalis paitients

Protocol summary

Study aim
Comparison of efficacy and side effects of oral calcitriol pulse therapy with oral daily calcitriol method

Design
In this study, patients underwent chronic hemodialysis will be randomized into two groups: patients continue receiving oral calcitriol, patients receiving oral calcitriol pulse therapy three times in a week. Finally, level of serum calcium, phosphorous and parathormone will be compared in two groups.

Settings and conduct
The study will be done as clinical trial in Dr. Sheikh hospital, Mashhad.

Participants/Inclusion and exclusion criteria
Inclusion criteria are included: Patients with chronic kidney disease (CKD) who are under chronic hemodialysis and need to receive Calcitriol for secondary hyperparathyroidism Age less than 18 years Serum bicarbonate more than 15 mEq/L Serum albumin more than 3 g/dl Hemoglobin more than 8 g/dl Exclusion criteria are included: Primary metabolic disorder Intestinal malabsorption Endocrine or liver disease Malignancies Receiving corticosteroid Receiving rhGH Hypocalcemia or hypercalcemia hypophosphatemia or hyperphosphatemia

Intervention groups
Intervention group: Oral calcitriol pulse therapy (0.75 micro gram per kilogram), three times weekly Control group: Oral daily calcitriol (0.25 micro gram per kilogram daily)

Main outcome variables
Level of calcium, phosphorous, alkaline phosphatase, vitamin D, parathormone.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20111024007892N10**
Registration date: **2022-04-12, 1401/01/23**
Registration timing: **retrospective**

Last update: **2022-04-12, 1401/01/23**
Update count: **0**

Registration date
2022-04-12, 1401/01/23

Registrant information
Name
Anoosh Azarfar
Name of organization / entity
Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-12-21, 1399/10/01
Expected recruitment end date
2021-04-21, 1400/02/01
Actual recruitment start date
2021-01-20, 1399/11/01
Actual recruitment end date
2021-03-21, 1400/01/01
Trial completion date
2022-02-12, 1400/11/23

Scientific title
Comparison the effect of oral calcitriol pulse therapy with oral daily calcitriol method in hemodiyalis paitients

Public title
Effect of oral calcitriol pulse therapy in comparison with oral daily calcitriol method in hemodiyalis paitients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic kidney disease (CKD) who are under chronic hemodialysis and need to receive Calcitriol for secondary hyperparathyroidism Age less than 18 years Serum bicarbonate more than 15 mEq/L Serum albumin more than 3 g/dl Hemoglobin more than 8 g/dl
Exclusion criteria:
Primary metabolic disorder Intestinal malabsorption Endocrine or liver disease Malignancies Receiving corticosteroid Receiving rhGH Hypocalcemia or hypercalcemia hypophosphatemia or hyperphosphatemia
Age
From **1 year** old to **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **20**
Actual sample size reached: **21**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be allocated to oral calcitriol pulse therapy or oral daily calcitriol groups, by block randomization with block size of 4. In each block, patients of each group will be exist. The order of blocks will be determined randomly in oral calcitriol pulse therapy or oral daily calcitriol groups and subjects will allocated sequentially with order of admitting. Random allocation rule method was used for determination of sequences. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients receive drugs (intervention or control groups) in closed pockets which are coded and patients are not aware of their contents. Coding will be done by one of the colleagues of the study and patient will be blind for type of drugs.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Mashhad University of Medical Sciences
Street address
Daneshgah
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2020-09-22, 1399/07/01
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.442

Health conditions studied

1

Description of health condition studied
Secondary hyperparathyroidism of renal origin
ICD-10 code
GB90.4
ICD-10 code description
Secondary hyperparathyroidism of renal origin

Primary outcomes

1

Description
Serum level of calcium
Timepoint
Baseline and one month after intervention
Method of measurement
laboratory measurement in blood sample

2

Description
Serum level of phosphorous
Timepoint
Baseline and one month after intervention
Method of measurement
laboratory measurement in blood sample

3

Description
Serum level of vitamin D
Timepoint
Baseline and one month after intervention
Method of measurement
laboratory measurement in blood sample

4

Description
Serum level of alkaline phosphatase
Timepoint
Baseline and one month after intervention
Method of measurement
laboratory measurement in blood sample

5

Description
Serum level of parathormone
Timepoint
Baseline and one month after intervention
Method of measurement
laboratory measurement in blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral calcitriol pulse therapy (0.75 micro gram per kilogram), three times weekly
Category
Treatment - Drugs

2

Description
Control group: Oral daily calcitriol (0.25 micro gram per kilogram daily)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Sheikh Hospital
Full name of responsible person
Anoush Azarfar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Majid Ghayour-Mobarhan
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Anoush Azarfar
Position
Associated Professor
Latest degree
Subspecialist
Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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sub-specialist resident

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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 data

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data of clinical trial in analysis will be published in an article after blinding patients' data

When the data will become available and for how long
unlimited from publishing

To whom data/document is available
researchers in medical universities

Under which criteria data/document could be used
data are specific for this study and is not reusable

From where data/document is obtainable
request by email to corresponding author

What processes are involved for a request to access data/document
sending request to email and response after one week

Comments