

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison the effect of oral calcitriol pulse therapy with oral daily calcitriol method in hemodialysis patients

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

Country

Iran (Islamic Republic of)

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+98 51 1606 1227

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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 hemodialysis patients

Public title

Effect of oral calcitriol pulse therapy in comparison with oral daily calcitriol method in hemodialysis patients

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

Street address

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

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

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Person responsible for scientific inquiries

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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 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