

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Evaluation of the Efficacy of Calcitriol Compared to Calcitriol plus Cinacalcet in the Treatment of Severe Secondary Hyperparathyroidism in Hemodialysis Patients Referred to Dialysis Centers in Gorgan

Protocol summary

Study aim

Determination of the effect of Calcitriol in comparison with Calcitriol plus Cinacalcet in treatment of severe secondary hyperparathyroidism in dialysis patients

Design

A randomized, phase II, single-blinded clinical trial with a parallel group includes 70 patients in which to randomize the samples with a randomized block design, four blocks is used.

Settings and conduct

Dialysis patients with severe secondary hyperparathyroidism who are eligible to participate in the study referred to dialysis centers in Gorgan are randomly divided into the two intervention groups: A) Rocaltrol and (B Cinacalcet + Rocaltrol. This study is single-blinded that the person who that the person who compares the groups and analyses the results of the study are unaware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: over 18 years old; dialysis for at least 3 months; iPTH levels above 800 pg/dL (severe secondary hyperparathyroidism); Do not take medications that have interactions with studied medications; No known hypersensitivity reaction to the drugs; No known liver disease; Calcium levels > 8.4 mg/dL. Exclusion criteria: any type of cancer in different parts of the body; Side effects of the medications; Diseases causing hypercalcemia; History of parathyroidectomy; Presence of parathyroid adenoma; Pregnant mothers or lactating women or females of childbearing age without use of contraception.

Intervention groups

Intervention group A: Receiving Calcitriol 1 mg orally every other night and intervention group B: Receiving Calcitriol 1 mg orally every other night plus Cinacalcet 30 mg orally daily.

Main outcome variables

Decreased parathyroid hormone levels and decreased serum phosphorus and calcium levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200218046533N1**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **prospective**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

Registration date

2020-05-31, 1399/03/11

Registrant information

Name

Saeid Amirkhanloo

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 17 3225 1502

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-01, 1399/03/12

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Evaluation of the Efficacy of Calcitriol Compared to Calcitriol plus Cinacalcet in the Treatment of Severe Secondary Hyperparathyroidism in Hemodialysis Patients Referred to Dialysis Centers in Gorgan

Public title
Efficacy of Cinacalcet in the Treatment of Secondary Hyperparathyroidism

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Aged 18 years and more; Dialysis for at least 3 months; iPTH levels above 800 pg/dL (severe secondary hyperparathyroidism); Do not take medications that have drug interactions such as flecainide, thioridazine, tricyclic antidepressants due to the effect of Cinacalcet on the P-450 cytochrome; No hypersensitivity reaction to the drugs used in the study; No liver disease; Calcium levels > 8.4 mg/dL.
Exclusion criteria:
Any evidence of cancer in different parts of the body; Side effects of the medications used during the study period; Diseases causing hypercalcemia; History of parathyroidectomy; Presence of parathyroid adenoma (to be confirmed by parathyroid scan); Pregnant mothers or lactating women or females of childbearing age who do not currently use contraception.

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
2

Groups that have been masked

- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomize the samples with a randomized block design, four blocks is used, so that one of the blocks is first selected randomly (for example, with a dice) and according to its order, the samples are allocated to two groups: A) for receiving Rocaltrol and (B receiving Cinacalcet + Rocaltrol.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is single-blind so the person who compares the results and analyses the data of the study will be unaware of the intervention.

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Ethics committee of Golestan University of Medical Sciences
Street address
Gorgan-Sari headway, beginning of Shast Kola road, Golestan University of Medical Sciences
City
Gorgan
Province
Golestan
Postal code
4918936316
Approval date
2019-05-19, 1398/02/29
Ethics committee reference number
IR.GOUMS.REC.1398.042

Health conditions studied

1
Description of health condition studied
Secondary hyperparathyroidism
ICD-10 code
N25.81
ICD-10 code description
Secondary hyperparathyroidism of renal origin

Primary outcomes

1
Description
Decreased parathyroid hormone levels
Timepoint
Before study and 3 and 6 months after treatment
Method of measurement
Blood test

Secondary outcomes

1
Description
Decreased serum phosphorus and calcium levels
Timepoint
Before study and 3 and 6 months after treatment
Method of measurement
Blood test

Intervention groups

1

Description

Intervention group A: Receiving Calcitriol 1 mg orally every other night

Category

Treatment - Drugs

2

Description

Intervention group B: Receiving Calcitriol 1 mg orally every other night plus Cinacalcet 30 mg orally daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

5th Azar Hospital

Full name of responsible person

Saeid Amirkhanlou

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2

Recruitment center

Name of recruitment center

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Sedigheh Ebrahimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about main outcomes of the study

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Researchers in universities and scientific and research centers

Under which criteria data/document could be used

In order to improve the treatment of the disease and subsequent research and with the permission of the authors

From where data/document is obtainable

Department of internal medicine of Golestan university of medical sciences

What processes are involved for a request to access data/document

Sending the request in writing or by email to the authors

Comments