Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 eligibile 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 parathyroidctomy; 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 parathyroidctomy; 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
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Sponsors / Funding sources

1

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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
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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