Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

A Comparative Study on the Effect of Calcitriol and Cinacalcet on Hyperparathyroidism in ESRD Patients

Protocol summary

Study aim
Detection of serum level changes of calcium / phosphate /parathyroid hormone in two groups of study (calciteriol and cinacalcate)

Design
Randomized clinical trial (Phase 3) of two arms, parallel with Cinacalcate and Calciteriol groups and double blind with 30-person groups

Settings and conduct
This randomized double-blind clinical trial study was performed to evaluate the parameters of calcium, phosphorus and parathyroid hormone (PTH) before and 8 weeks after intervention in Hajar hospital of Shahrekord. Patients were divided into two groups of 30 persons of Cinacalcate and Calciteriol. Patients in this study were unaware of placement in the Calcitriol and Cinacalcet groups. The statistical analysis of the groups was performed based on the code and the statistician is blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Consent to participate in the study, Having end-stage renal disease, Patients undergoing hemodialysis. Non-inclusion criteria: Parathyroid hormone less than 300 pg / ml Calcium higher than 10 mg / dl

Intervention groups
Group 1 receive Cinacalcate and group 2 receive Calciteriol

Main outcome variables
Calcium/phophate/Parathyroid hormone (PTH)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190702044076N1**
Registration date: **2019-09-21, 1398/06/30**
Registration timing: **retrospective**
Last update: **2019-09-21, 1398/06/30**
Update count: **0**

Registration date
2019-09-21, 1398/06/30

Registrant information

Name
Faranak sadat Filsous

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3778 8907

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hamidnasri@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-03, 1397/04/12

Expected recruitment end date
2019-07-03, 1398/04/12

Actual recruitment start date
2018-07-03, 1397/04/12

Actual recruitment end date
2019-07-03, 1398/04/12

Trial completion date
2019-08-03, 1398/05/12

Scientific title
A Comparative Study on the Effect of Calcitriol and Cinacalcet on Hyperparathyroidism in ESRD Patients

Public title
Effect of Calciterol and Cinacalcate on hyperparathyroidism

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study Having end-stage renal disease Patients undergoing hemodialysis

Exclusion criteria:

Parathyroid hormone less than 300 pg / ml Calcium higher than 10 mg / dl

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the participants were given two-digit codes from 01 to 60. Then, using the website www.Randomization.com, the statistical consultant provided two sets of codes, the first set assigned as the Calcitriol group and the second, Cinacalcet group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in this study were unaware of placement in the Calcitriol and Cinacalcet groups. The statistical analysis of the groups was performed based on the code and the statistician is blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord university

Street address

Num 21/shahid yar mohammadi alley/Bagh ziar Blve

City

Esfahan

Province

Isfehan

Postal code

8177774564

Approval date

2018-04-22, 1397/02/02

Ethics committee reference number

IR.SKUMS.REC.1397.026

Health conditions studied

1

Description of health condition studied

Hyperparathyroidism

ICD-10 code

E21

ICD-10 code description

Hyperparathyroidism and other disorders of parathyroid gland

Primary outcomes

1

Description

Calcium

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Serum levels of blood sample

2

Description

Phosphate

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Serum levels of blood sample

3

Description

Parathyroid hormone

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Serum levels of blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The group receiving Cinaaclate (AMGEN pharmaceutical company of Netherland) receives 30 mg daily. The ultimate target of this group is the PTH level between 150 Pg / ml and 300 Pg / ml. The dose can be increased to 90 mg daily or three 30 mg tablets daily if elevated. This treatment is continued for up to 8 weeks after starting the study and then the levels

of phosphate, calcium and parathyroid hormone are measured.

Category

Treatment - Drugs

2

Description

Intervention group 2: The group receiving Calcitriol (Zahravi Pharmaceutical Company of Iran) receives 0.5-1.5 mg daily. The ultimate target of this group is the PTH level between 300 Pg / ml and 600 Pg / ml. The dose may be increased to 1.5–3 mg daily if elevated. This treatment is continued for up to 8 weeks after starting the study and then the levels of phosphate, calcium and parathyroid hormone are measured.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar hospital in Shahrekord

Full name of responsible person
Faranak Sadat Filsouf

Street address
Parastar street

City
Shahrekord

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Chahar-Mahal-va-Bakhtiari

Postal code
8813833435

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+98 38 3222 5505

Email
Hajar-Hospital@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Saeed Mardani

Street address
Farabi street

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8815716191

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s-mardani@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahre-kord University of Medical Sciences

Proportion provided by this source
70

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
Shahre-kord University of Medical Sciences

Full name of responsible person
Faranak Sadat Filsouf

Position
Medical doctor

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Internist

Latest degree

Subspecialist

Other areas of specialty/work

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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

privacy

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments