Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

Phone
+98 31 3778 8907

Email address
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

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813833435

Phone

+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

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815716191

Phone

+98 38 3333 4818

Email

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

Street address

Bagh Ziar

City

Isfahan

Province

Isfehan

Postal code

8177775364

Phone

+98 31 3778 8907

Email

Frankfaranak@yahoo.com

Person responsible for scientific 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

Street address

Bagh Ziar street

City

Isfahan
Province
Isfehan
Postal code
788885764
Phone
+98 31 3778 8907
Email
Frankfaranak@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Saeed Mardani
Position
Internist
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Farabi
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
881576191
Phone
+98 38 3334 8418
Email
s-mardani@yahoo.om

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