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Changes in cardiovascular calcification after denosumab in dialysis patients with secondary hyperparathyroidism and low bone mass

Submission date
02/10/2018

Recruitment status
No longer recruiting

Registration date
01/11/2018

Overall study status
Completed

Last Edited
09/08/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In a previous study of the drug denosumab for the treatment of severe hyperparathyroidism (too much parathyroid hormone) in patients with low bone mass undergoing dialysis, patients could benefit from bone mass gain and bone pain relief. In dialysis patients, this drug is relatively safe because each dialysis session delivers calcium into the circulation. However, reportedly, calcium and active vitamin D given to prevent hypocalcemia (low blood calcium) can lead to ectopic calcification (calcium build up). Using appropriate calcium dialysate (dialysis fluid) to make total body calcium as balanced as possible, denosumab could cause bone mass gain and reduce soft tissue and vessel calcification. This study aims to recruit patients with end stage renal (kidney) disease with hyperparathyroidism and low bone mass. The goal is to find whether denosumab could slow coronary artery calcification in patients with hyperparathyroidism undergoing regular dialysis.

Who can participate?
Patients aged 18 and over with end stage renal disease with hyperparathyroidism and low bone mass

What does the study involve?
Participants are allocated to one of two groups by their wishes, to receive either denosumab or not. All participants attend for a CT scan of the heart to measure blood vessel calcification. Participants attend for a review at 6 months.

What are the possible benefits and risks of participating?
The participants could benefit from free CT scans to monitor their heart. The participants who receive denosumab are closely monitored during the dialysis process. However, there could still be a risk of hypocalcemia.

Where is the study run from?
Kaohsiung Veterans General Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
September 2013 to August 2018

Who is funding the study?
Kaohsiung Veterans General Hospital (Taiwan)

Who is the main contact?
Dr Chien-Liang Chen
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KSC104-051

Study information

Scientific Title
Changes in cardiovascular calcification after denosumab in dialysis patients with secondary hyperparathyroidism and low bone mass

Study objectives
The effect of denosumab on vascular calcification in patients with chronic renal failure patients with low bone mass has been a subject of interest. The purpose of this investigation is to determine changes in vascular calcification after the administration of denosumab by using fast-

gated helical computed axial tomographic imaging to measure coronary and abdomen aorta calcification.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kaohsiung V.G.H. Institutional Review Board, 17/09/2013, ref: VGHKS-CT18-CT8-19

Study design
Non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Patients with ESRD undergoing dialysis with severe hyperparathyroidism and low bone mass

Interventions
The effect of denosumab on vascular calcification in patients with chronic renal failure patients with low bone mass has been a subject of interest. The purpose of this investigation is to determine changes in vascular calcification after the administration of denosumab by using fast-gated helical computed axial tomographic imaging to measure coronary and abdomen aorta calcification.

Participants are allocated to one of two groups by their wishes, to receive either 60 mg denosumab (denosumab group) or conventional treatment (control group). All participants have a screening visit combined with a baseline visit, and if happy to participate and they will attend for a CT scan of the heart at baseline and at the 6-month follow-up examination to determine bone mineral density and blood vessel calcification.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Denosumab

Primary outcome measure
Coronary and abdomen aorta calcification measured using fast-gated helical computed axial tomographic imaging at baseline and 6 months

Secondary outcome measures
Osteopenia measured using dual-energy X-ray absorptiometry (DEXA) at baseline and 6 months

Overall study start date
17/09/2013

Completion date
08/08/2018

Eligibility

Key inclusion criteria
In accordance with the regulatory guidelines, the patients were enrolled in the peritoneal dialysis or hemodialysis patient groups. Key inclusion criteria were age >18 years, normal laboratory tests at screening and baseline, and clinically acceptable physical examination and electrocardiograph results at screening. The study protocol was therefore amended to include requirements for daily supplementation of calcium and calcitriol according to standard dialysis guideline in all subjects with ESRD with low bone mass and a history of iPTH>800 pg/mL. All of the patients had been receiving renal replacement therapy, had various degrees of osteopenia with bone mineral densities, which were measured by dual-energy X-ray absorptiometry (DEXA); furthermore, all patients had a forearm, femoral neck or lumbar spine T score lower than -2.5 SD, indicative of low bone mass.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
21

Total final enrolment
42

Key exclusion criteria

Key exclusion criteria were known sensitivity to any study treatment, unstable medical condition, history of malignancy, active infection, pregnancy, lactation, nursing, parathyroidectomy with parathyromatosis, drug abuse at screening, and aluminum levels >20 µg /L

Date of first enrolment
08/10/2013

Date of final enrolment
16/09/2016

Locations

Countries of recruitment
Taiwan

Study participating centre
Kaohsiung Veterans General Hospital
386 Ta-chung first section road
Kaohsiung City
Taiwan
81410

Sponsor information

Organisation
Kaohsiung Veterans General Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.vghks.gov.tw/

ROR
https://ror.org/04jedda80

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Kaohsiung Veterans General Hospital, VGHKS 104-051 and VGHKS105-080

Results and Publications

Publication and dissemination plan
Submission to journal

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Chien-Liang Chen (cclchen1@vghks.gov.tw).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			09/08/2022	No	No
Results article		01/08/2020	09/08/2022	Yes	No