ISRCTN10043222 https://doi.org/10.1186/ISRCTN10043222

Safety study of a large dose of vitamin D administered to hemodialysis patients and assessment of its effects on the parameters of bone abnormalities

Submission date
27/12/2021

Recruitment status
No longer recruiting

Registration date
18/02/2022

Overall study status
Completed

Last Edited
05/03/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study arms
Hemodialysis is a procedure where a dialysis machine and a special filter called an artificial kidney, or a dialyzer, are used to clean the blood. Hemodialysis patients are usually low in vitamin D3 (VD3) and active VD3. However, they rarely receive VD3. Instead, they are usually prescribed active vitamin D because the kidneys can no longer activate VD3. The compliance to active VD treatment is not good and it is thought to cause vascular calcifications (mineral deposits on the walls of the arteries and veins). Hemodialysis patients also frequently have high levels of intact parathyroid hormone (iPTH), which causes damage to the bones.
The usual treatment given is active VD and calcimimetics (drugs that mimic the action of calcium on tissues). Studies have shown that VD3 is very beneficial for dialysis patients. It has the ability to restore the VD3 store and decrease the blood level of iPTH. In other studies it was shown that it can lead to increased levels of active VD, but there is no published guideline on which treatment to follow to be able to reach these targets.
The aim of this study is to use large doses of VD3 (also used in other studies) over a long period and assess the safety of such a practice and observe the effects on bones.

Who can participate?
Hemodialysis patients with hyperparathyroidism (where the parathyroid glands become overactive and release too much parathyroid hormone)

What does the study involve?
Participants receive a large oral dose of vitamin D3 every month for 9 consecutive months after dialysis. Blood samples are taken for tests at the start and every 3 months until the end of the study.

What are the possible benefits and risks of participating?
The benefits include replenishment of vitamin D3 stores. No risks are expected.

Where is the study run from?
Sharjah University Hospital (United Arab Emirates)

When is the study starting and how long is it expected to run for?
August 2019 to December 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Adnane Guella
guella@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Adnane Guella

ORCID ID
https://orcid.org/0000-0002-4026-4268

Contact details
UAE
Sharjah
United Arab Emirates
72772
+971 (0)562408484
adnane.guella@uhs.ae

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HD-VD3

Study information

Scientific Title
Monthly administration of high-dose vitamin D3 in hemodialysis patients

Study objectives

Administration of Vitamin D3 in a large dose for a long period may obviate the administration of active vitamin D which is known to cause vascular calcification. Moreover, this practice may stimulate endogenous production of 1,25 dihydroxy vitamin D3 [1,25(OH)2 Vit D3]. Its effect on reducing intact parathormone (iPTH) was reported, however, the target level of serum level of cholecalciferol to obtain a decrease in iPTH is not established.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/10/2019, Research Ethics Committee of the University Hospital of Sharjah (PO Box 72772, Sharjah, United Arab Emirates; +971(6) 505 8555; adnane.guella@uhs.ae), ref: UHS-HERC-B042-161019

Study design
Single-center single-arm interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypovitaminosis D and secondary hyperparathyroidism

Interventions
Hemodialysis patients with secondary hyperparathyroidism and not on either active VD3 nor calcimimetics are included in the study to receive a large oral dose of vitamin D3 (300,000 units) every month for 9 consecutive months post-dialysis. Serum levels of 25(OH)VD, 1,25(OH)2 VD, calcium, phosphorus, alkaline phosphatase and iPTH are measured at the start and every 3 months until the end of the study.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Measured at 0, 3, 6 and 9 months:
1. Serum levels of 25(OH)VD measured using the LIAISON® 25 OH Vitamin D assay
2. Serum levels of 1,25(OH)2 VD measured using the LIAISON® XL 1,25 Dihydroxyvitamin D assay
3. Serum levels of iPTH measured using the Atellica IM PTH assay

Key secondary outcome(s))
Measured at 0, 3, 6 and 9 months:
1. Serum calcium measured using the Atellica® CH Calcium (Ca) assay

2. Serum phosphorus measured using the Atellica™ CH Inorganic Phosphorus (IP) assay
3. Serum alkaline phosphatase measured using the Atellica™ CH Alkaline Phosphatase, concentrated (ALP_2c) assay

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Hemodialysis patients
2. On dialysis for more than 1 year
3. Not on active Vitamin D
4. Not on calcimimetics

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
23

Key exclusion criteria
1. Tertiary hyperparathyroidism
2. Ongoing debilitating condition (e.g. cancer)

Date of first enrolment
01/03/2020

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
United Arab Emirates

Study participating centre
Sharjah University Hospital
Sharjah

United Arab Emirates
72772

Sponsor information

Organisation
University of Sharjah

ROR
https://ror.org/00engpz63

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Dr Adnane Guella (guella@gmail.com). Data will be available for 1 year from March 2022 by email. All the blood investigations studied can be available for sharing, as well as consent from participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/03/2023	05/03/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version .01	08/07/2019	18/08/2022	No	No