

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

<b>Submission date</b> 27/12/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/03/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
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)<sub>2</sub> Vit D<sub>3</sub>]. 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

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Hypovitaminosis D and secondary hyperparathyroidism

**Interventions**

Hemodialysis patients with secondary hyperparathyroidism and not on either active VD<sub>3</sub> nor calcimimetics are included in the study to receive a large oral dose of vitamin D<sub>3</sub> (300,000 units) every month for 9 consecutive months post-dialysis. Serum levels of 25(OH)VD, 1,25(OH)<sub>2</sub> 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 measure**

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)<sub>2</sub> VD measured using the LIAISON® XL 1,25 Dihydroxyvitamin D assay
3. Serum levels of iPTH measured using the Atellica IM PTH assay

### **Secondary outcome measures**

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

### **Overall study start date**

01/08/2019

### **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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

48

### **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

**Sponsor details**

UAE

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aabdelkarim@sharjah.ac.ae

**Sponsor type**

Government

**Website**

<http://www.sharjah.ac.ae/en/Pages/default.aspx>

**ROR**

<https://ror.org/00engpz63>

## Funder(s)

**Funder type**

Other

## Funder Name

Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. No additional documents are available or published online.

### Intention to publish date

01/03/2022

### 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?
<a href="#">Protocol file</a>	version .01	08/07/2019	18/08/2022	No	No
<a href="#">Results article</a>		30/03/2023	05/03/2024	Yes	No