

You may be eligible for our study if you have:

- Primary Hyperparathyroidism
- Low Vitamin D levels

You will be ineligible if you have a history of:

- Kidney or Liver disease
- Long term use of steroid medications, some anti-seizure medication or current use of Cinacalcet
- Organ transplantation
- GI diseases such as Crohns or Celiac Disease
- Malignancy (other than cured basal or squamous cell skin carcinoma) within the last 5 years
- Sarcoidosis
- HIV/AIDS

Please contact our Study Coordinator for more information, or to talk about participating in the study:

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This study has been reviewed and approved by the Columbia University Medical Center Institutional Review Board:

AAAF1797

Treatment of Vitamin D Deficiency in patients with PHPT



A RESEARCH STUDY
SPONSORED BY:

The National Institutes
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AND

The Columbia University
Medical Center
**Metabolic Bone Disease
Program**

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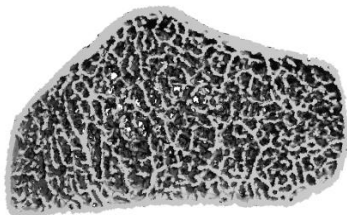
IRB-AAAF1797

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for use until: 02/08/2015

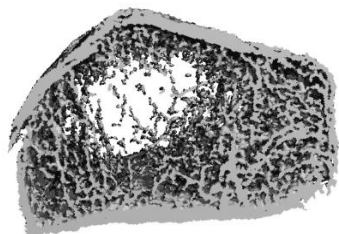
Vitamin D and PHPT

Many patients with mild Primary Hyperparathyroidism (PHPT) have Vitamin D deficiency.

Both PHPT and Vitamin D deficiency can weaken bones and cause osteoporosis. Recent medical guidelines recommend treating patients with PHPT and low vitamin D levels with vitamin D. Treatment with vitamin D is particularly important in PHPT patients undergoing surgery to prevent postsurgical complications, such as a low blood calcium. This study is designed to determine how vitamin D should be replaced in patients with PHPT and low vitamin D.



Healthy wrist bone as seen on HR-pQCT



Wrist bone with osteoporosis as seen on HR-pQCT

PHPT Vitamin D Repletion Study

Study Description

The purpose of this study is to investigate the impact of two different vitamin D repletion regimens over a 6 month period in patients with PHPT and low vitamin D.

This is a randomized controlled trial which means that you will either:

- 1) Receive active vitamin D treatment at baseline (80% of participants) + a daily multivitamin with vitamin D

or

- 2) Receive a placebo at baseline (20% of participants) + a daily multivitamin with vitamin D

Group 1 or 2 assignment is by chance (randomized). Neither you nor your physician will know which group you are in until the 6 month time point.

Over the course of the study, participants will undergo treatment with vitamin D and participate in the following procedures to measure their response to treatment:

- Bone Density Test*
- High resolution CT scan of the arm and leg (HR-pQCT) and CT scan of the lumbar spine (cQCT)*
- Abdominal x-ray to check for the presence of kidney stones*
- Questionnaires
- Blood & urine sample collections

*Only performed at the baseline and 6 month visits

Frequently Asked Questions

How much radiation might I be exposed to from the study?

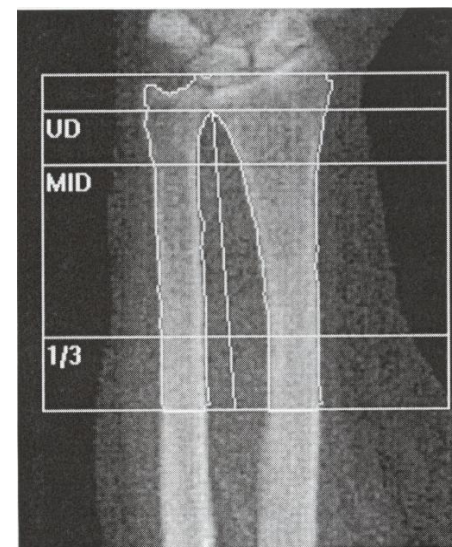
- The total dose from completing all imaging scans is considered safe exposure for most people.

How will my participation be compensated?

- Each participant receives \$75 for completing each study visit (a total of \$300 for all four study visits), and later receives a summary of all results.

What will my results include?

- The results and descriptions of your DXA and HR-pQCT images (see figures left and below) and laboratory results.



Total Bone Density by DXA