

Evaluation of vitamin D intake and serum 25 hydroxyvitamin D concentration on calcium metabolism

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| Submission date 17/05/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 24/06/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 02/05/2017 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Vitamin D is essential for good health, because it helps our bodies to absorb calcium from the diet. There is a lot of evidence that having enough vitamin D can help prevent against many diseases, such as heart disease, bone diseases and cancer. Although vitamins generally come from the diet, in the case of vitamin D, the majority of people actually get most of it from sunlight. Almost every cell in the body contains a vitamin D receptor that is vital for a variety of functions. Low vitamin D therefore can prevent tissues from carrying out their normal functions, which can lead to a range of long-term health conditions, such as weak bones, heart disease and problems with the immune system. The Pure North S'Energy Foundation (Pure North) is a not-for-profit organization that provides preventative health and wellness services. The Pure North program works through screening patients to identify health needs and nutritional deficiencies, including vitamin D, in order to offer advice about how to address any problems (such as with vitamin D supplements for those with low levels of vitamin D).

Who can participate?

All patients seen at the Pure North clinic between 2012 and 2015 who had follow up visits 6-18 months after their first visit.

What does the study involve?

Participants provide consent for their medical information from the Pure North clinic visits to be accessed from the database by the study team. Patients do not need to attend any clinic visits for the study as all data is taken from the Pure North database for analysis. Blood work results testing vitamin D levels in the blood are assessed in order to evaluate the effect of vitamin D supplements on vitamin D status, calcium regulation, as well as kidney, liver and immune system function.

What are the possible benefits and risks of participating?

There are no direct benefits or risks involves for participants taking part in this study.

Where is the study run from?
Pure North S'Energy Foundation (Canada)

When is the study starting and how long is it expected to run for?
September 2012 to January 2016

Who is funding the study?
Pure North S'Energy Foundation (Canada)

Who is the main contact?
Dr Michael Holick
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Safety2016

Study information

Scientific Title
Evaluation of vitamin D3 intakes up to 15,000 international units/day and serum 25 hydroxyvitamin D concentrations up to 300 nmol/L on calcium metabolism in a community setting

Study objectives
The aim of this study is to characterize the effect of vitamin D supplementation at doses up to 15,000 IU/d in a community-based program on vitamin D status, calcium homeostasis as well as on kidney, liver and immune function.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Due to the nature of this trial (database analysis), no ethics approval is required

Study design

Retrospective cohort database analysis

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Vitamin D deficiency

Interventions

This study is a retrospective evaluation of blood work and clinical data collected by the Pure North program.

Data included in the database were collected for new participants who entered the program between 2012 and 2015 and who had follow-up within a 6-18 month period after their first visit. During this timeframe all laboratory analyses were conducted by a single, certified and accredited clinical laboratory, Doctor's Data (St. Charles, IL).

Participants are assessed at each visit to the clinic, typically every 12 months, for the following:

1. Biometric measurements including blood pressure, height, weight, BMI
2. Clinical intake with a Health Care Professional, either a doctor or a nurse practitioner, including medical history, current medications, complaints and health goals
3. Blood work for four different categories of biochemical parameters involving vitamin D safety including; calcium homeostasis [serum calcium, 25(OH)D, PTH and urinary calcium: creatinine ratio, inflammation [high-sensitivity C-reactive protein (hs-CRP)], liver function [Alanine Amino-Transferase (ALT), Gamma Glutamyl Transferase (GGT)] and kidney function [Creatinine, estimated Glomerular Filtration Rate (eGFR)]
4. Completion of a health questionnaire including demographic data and self-reported health assessments

Participants results are stored in the database and are categorised according to their gender, age, BMI, vitamin D intake level and serum 25(OH)D status. The results are then analysed from all clinic visits attended to examine the influence of various biomarkers, including vitamin D dose and 25(OH)D concentrations, on measures of calcium homeostasis and adjunctive safety measures (liver and kidney function and inflammation).

Intervention Type

Supplement

Primary outcome(s)

1. Calcium homeostasis is determined from serum calcium, 25(OH)D, PTH and urinary calcium: creatinine ratio at clinic visits every 12 months for 1 year (2 visits) through medical record review
2. Inflammation is determined from serum high-sensitivity C-reactive protein (hs-CRP) levels measured at clinic visits every 12 months for 1 year (2 visits) through medical record review
3. Liver function is determined from serum Alanine Amino-Transferase (ALT) and Gamma Glutamyl Transferase (GGT) levels measured at clinic visits every 12 months for 1 year (2 visits) through medical record review

4. Kidney function determined from estimated Glomerular Filtration Rate (eGFR) measured at clinic visits every 12 months for 1 year (2 visits) through medical record review

Key secondary outcome(s))

No secondary outcome measures

Completion date

22/01/2016

Eligibility

Key inclusion criteria

All patients at the Pure North clinic between 2012 and 2015 and who had follow-up visits within a 6-18 month period after their first visit.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

None

Date of first enrolment

11/03/2012

Date of final enrolment

26/09/2015

Locations

Countries of recruitment

Canada

Study participating centre

Pure North S'Energy Foundation

326 11 Ave SW #800

Calgary

Canada

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Sponsor information

Organisation

Pure North S'Energy Foundation

ROR

<https://ror.org/0364jg040>

Funder(s)

Funder type

Industry

Funder Name

Pure North S'Energy Foundation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 13/04/2017 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |