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

Submission date
17/05/2016

Recruitment status
No longer recruiting

Registration date
24/06/2016

Overall study status
Completed

Last Edited
02/05/2017

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 anaylsis

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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 analyses 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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/09/2012

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

Age group
Mixed

Sex
Both

Target number of participants
3500

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

Sponsor details
Suite 800, 326
11th Ave. SW
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0364jg040

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Publication and dissemination plan
No current plans to publish the study results.

Intention to publish date

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