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The influence of hypovitaminosis D on iron deficiency in healthy women

Submission date
21/09/2017

Recruitment status
No longer recruiting

Registration date
09/10/2017

Overall study status
Completed

Last Edited
03/10/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hypovitaminosis D (a deficiency in Vitamin D, a nutrient that comes from sunlight) has been associated with anemia in patients with chronic diseases and also in healthy populations. One of the explanations for this association is the action of vitamin D on iron metabolism, which influences the absorption and mobilisation of iron, mainly through inflammatory mechanisms. It is not yet known if vitamin D could directly influence the body iron storage. The aim of this study was to verify the correlation between vitamin D levels and body iron store in a population of healthy adult women.

Who can participate?
Women aged 18 and older with chronic diseases.

What does the study involve?
Participants are measured for their body iron content and their vitamin D levels measured which is retrieved from a public database. The data is then analysed using a statistical model.

What are the possible benefits and risks of participating?
There are no benefits or risks with participating.

Where is the study run from?
Instituto De Medicina Integral Professor Fernando Figueira (Brazil)

When is the study starting and how long is it expected to run for?
November 2016 to December 2016

Who is funding the study?
Investigator initiated and funded (Brazil)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Plataforma Brasil. CAAE: 60849916.3.0000.5201

Study information

Scientific Title
Influence of vitamin D on body iron store in healthy women from NHANES: a cross-sectional study using an econometric model of causal inference

Study objectives
Hypotheses:
1. Vitamin D levels have a positive correlation with body iron content in women.
2. Positive correlation functions between vitamin D levels and body iron content differ according to age, race, menstrual status and levels of parathyroid hormone.
3. Vitamin D has a cause-effect relationship on body iron content.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee on Research in Human Beings of the Institute of Integral Medicine, 05/12/2016, ref: Record number: 60849916.3.00005201

Study design

A cross-sectional population-based study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Hypovitaminosis D and iron deficiency

Interventions
The study is cross-sectional study. Participants have the variables of interested measured. This includes measurements for body iron content (calculated using Cook's formula) and 25hydroxivitamin D levels. There is no follow up. The data is retrieved from NHANES public datasets, which includes laboratory information of interest: levels of RsTf (soluble transferrin receptor), ferritin and 25hydroxivitamin D. No sample size calculation was performed, choosing to use all the observations that met the selection criteria in the years 2003-2004 and2005-2006.

Statistical analysis:
A predictive multivariate theoretical model, with Body Iron Store as dependent variable and 25 hydroxivitamin D as the predictive variable is designed. Statistical strategy to select covariables is not used, choosing, instead, saturated models that aim to estimate the coefficient of the predictive variable adjusted for the largest possible number of confounders. The following confounding covariables are: age, race, educational level, annual family income (USD/year), menstrual status, body mass index (BMI) (kg/m2), albumin level (g/dL), CRP level (mg/dL) and parathyroid hormone (PTH) level (pg/mL).

Initially, a simple linear regression model (Ordinary Least Squares – OLS) is used to evaluate the β coefficient of the correlation between 25OHD and BIS, which is then adjusted for sociodemographic, clinical, and laboratory covariables in a multiple linear regression model. For the evaluation of the possible effect modifiers, the model was stratified according to the subgroups of iron-sufficient and iron-deficient women. Next, vitamin D interaction terms, with age, race, PTH and menstrual status, are added, which are included in the multivariate models as products of 25OHD and each of these covariables.

Then, to access causal inference, we chose the econometric model proposed by Lewbel to identify the effect of endogeneity on dose-response correlation coefficients. According to the econometric rationale, if we can mathematically rule out the endogeneity bias, we can perform a causal inference.

Intervention Type

Other

Primary outcome measure
Vitamin D levels in correlation with body iron stores (BIS) are measured using patient data and a predictive model.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
01/11/2016

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Women older than 18 years old
2. Who did not have chronic diseases
3. In whom the results of 25-hydroxyvitamin D (25OHD)
4. Soluble transferrin receptor (sTfR)
5. Ferritin levels available
6. Chronic diseases as defined as the following a self-report of cancer, heart failure, pulmonary emphysema, chronic bronchitis, gastric or intestinal diseases; changes in laboratory markers of liver disease (aspartate aminotransferase greater than 121 U/L, alanine aminotransferase greater than 128 U/L and total bilirubin greater than 2.1 mg/dL) or renal disease (creatinine greater than 1.5 mg/dL); and the presence of a HIV-positive serology.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
3667

Key exclusion criteria
1. Women who reported undergoing iron supplementation in the last 3 months
2. Who had a positive pregnancy test or changes in the markers of malnutrition (albumin < 3.5 g /dL)
3. Inflammation (C-reactive protein (CRP) > 5.0 mg/dL) or iron overload (transferrin saturation > 45%)

Date of first enrolment
01/01/2017

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
Brazil

United States of America

Study participating centre
Instituto De Medicina Integral Professor Fernando Figueira
R. dos Coelhos, 300 - Boa Vista
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Sponsor information

Organisation
Instituto De Medicina Integral Professor Fernando Figueira

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01rtyyz33

Funder(s)

Funder type
Other

Funder Name
Investigator initated and funded

Results and Publications

Publication and dissemination plan
Planned publication of the results in the American Journal of Clinical Nutrition.

Intention to publish date
30/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Daniely Sobreira Cariry Barbosa (danycariry@hotmail.com)

IPD sharing plan summary
Available on request