

# The influence of hypovitaminosis D on iron deficiency in healthy women

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<b>Registration date</b> 09/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/10/2017	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?

Mrs Daneily Barbosa  
danycariry@hotmail.com

# Contact information

## Type(s)

Public

## Contact name

Mrs Daniely Barbosa

## Contact details

Rua Arlindo Gouveia

145

2502b

Recife

Brazil

50720595

+55 819 883 73784

danycariry@hotmail.com

# Additional identifiers

## Protocol serial number

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

**Study type(s)**

Other

**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 25hydroxvitamin 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 25hydroxvitamin 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 hydroxvitamin 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/m<sup>2</sup>), 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  $\beta$  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(s)**

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

**Key secondary outcome(s)**

There are no secondary outcome measures.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**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  
PE  
Recife  
Brazil  
50070-550

## Sponsor information

### Organisation

Instituto De Medicina Integral Professor Fernando Figueira

### ROR

<https://ror.org/01rtyyz33>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### 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](mailto:danycariry@hotmail.com))

### IPD sharing plan summary

Available on request