Description of practices regarding supplementation after HYPOvitaminosis-D investigation in middle-age community dwelling general population (HYPO-D Study)

First published: 21/12/2012

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Study Finalised

Administrative details

EU PAS number

EUPAS3260

Study ID

27493

DARWIN EU® study

No

Study countries

France

Study description

Rational:Severe chronic vitamin D depletion in adults causes osteomalacia. Moderate to severe 25-hydroxyvitamin D (25(OH)D) deficiency is frequent, probably underdiagnosed, and possibly associated with the increase of other health outcomes. However, except in specific populations, the effect of vitamin D supplementation in deficient patients is still debated. Our purpose was to compare health care use after vitamin D supplementation versus before in patients likely to have 25(OH)D deficiency.Design - A before-after cohort study in a young to middle-aged population of patients with a prescription of 25(OH)D dosage from their physician was conductedSetting - The Insurance Healthcare System of the Rhône-Alpes area (France) database was used to follow ambulatory patients reimbursed for a 25(OH)D assay between December 1st 2008 and January 31th 2009.Interventions - Data on healthcare use were extracted over 5 months before and 5 months after the assay, including physician visits and medical interventions, number and type of drug prescriptions, mean number of drug classes per distinct prescriptions, medical imaging use, biology exams use, presence incident sick leaves, and incident hospitalizations.Outcomes : An individual was considered “25(OH)D deficient” if they had a record of a vitamin D assay for a dosage of 25(OH)D followed by vitamin D supplementation (i.e. at least one occurrence of vitamin D2 or Vitamin D3 delivery in the 3 months after the assay). Patients who were not prescribed vitamin D after their assay were considered as “not 25(OH)D deficient” and became part of the control group. The index date was the date of supplementation for the 25(OH)D deficient group and the date of 25(OH)D assay for the reference group. We compared the evolution of extracted data between the before and the after period.

Study status

Finalised

Research institutions and networks

Institutions

Hospices Civils de Lyon

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anne-Marie SCHOTT

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/05/2010

Actual: 03/05/2010

Study start date

Planned: 07/06/2010

Actual: 07/06/2010

Data analysis start date
Planned: 07/11/2011

Actual: 07/11/2011

Date of final study report
Planned: 02/01/2012

Actual: 27/02/2014

Sources of funding

- Other

More details on funding

Hospices Civils de Lyon

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Our purpose was to compare health care use after vitamin D supplementation versus before in patients likely to have 25(OH)D deficiency.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A11CC) Vitamin D and analogues

Vitamin D and analogues

Medical condition to be studied

Vitamin D deficiency

Population studied

Short description of the study population

Patients aged 13–60 years who had a 25(OH)D assay between 1 December 2008 and 31 January 2009.

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

3.000

Study design details

Outcomes

Healthcare use comparison between pre and post-supplementation concerned: the number of physician visits and recorded medical interventions, of different drug prescriptions, of drug classes per distinct dates of prescription -defined by ATC codes, of medical of medical imaging exams, of incident sick leaves and cumulated days of leaves prescribed, and of incident hospitalizations.

Data analysis plan

The study population was described using mean and standard deviation for continuous variables and frequencies and proportions for discrete variables. The supplemented and the not supplemented groups were compared using t-test

when variables were continuous and Chi-square test when variables were discrete. Healthcare use within each group was compared before and after the index date using paired t-tests on the same sample for continuous variables, and Mc Nemar Chi-squared test for discrete variables. A threshold of 0.05 was used for statistical significancy.To adjust the comparison before-after supplementation for potential biases due to different types of healthcare users we used KML clustering. Analyses were performed using SAS Enterprise Guide V 4.3 (SAS Institute Inc. Cary, NC, USA). Longitudinal clustering was performed using R version 2.13.0 with KML package.

Documents

Study results

CailletPHN2014.pdf (639.24 KB)

Study, other information

CailletEJCN2013.pdf (376.86 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown