Bioequivalence study for vitamin D3 pharmacokinetic parameters following single oral administrations of vitamin D3 1000 IU with cyclodextrin and vitamin D3 1000 IU without cyclodextrin in Caucasian healthy volunteers

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON37168

Source
ToetsingOnline

Brief title
Vitamin D3 bioequivalence study

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Osteoporosis, porous bones

Research involving

Human

Sponsors and support

Primary sponsor: Institut de Recherches Internationales Servier I.R.I.S
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Bioequivalence, Cyclodextrin, Osteoporosis, Vitamin D3

Outcome measures

Primary outcome

bioequivalence for vitamin D3 pharmacokinetic (PK) parameters between a single oral administration of a capsule of vitamin D3 1000 IU as concentrate with cyclodextrin and a single oral administration of a capsule of vitamin D3 1000 IU as concentrate (i.e. cholecalciferol 25 µg) without cyclodextrin

Secondary outcome

To collect information on safety and tolerability of concentrate of vitamin D3 with RAMEB and concentrate of vitamin D3 without cyclodextrin.

Study description

Background summary

Vitamin D3 is used to prevent or correct a lack of vitamin D in the human body. In a normal situation, vitamin D can be synthesised by the human body by exposure of the body to sunlight. Also, vitamin D is obtained from ingested food. A lack of vitamin D may be caused by insufficient intake together with inadequate exposure of the body to sunlight or conditions that inhibit the uptake of vitamin D and is frequent in Europe. A lack of vitamin D may lead to a decreased bone mineralisation and finally to conditions that soften the bone. In addition, vitamin D has other functions in the body and a lack of vitamin D may play a role in cardiovascular diseases and cancer.

Study objective

The purpose of the study is to investigate whether the cyclodextrin added to the cholecalciferol formulation has an effect on the vitamin D3 availability in the body. Thus, it will be investigated if concentrations of vitamin D3 that are found in the blood following administration of a known formulation of stabilized vitamin D3 (without cyclodextrin) differ from those found following administration of vitamin D3 with cyclodextrin.

Study design

The actual investigation will consist of 2 treatments periods. There is a fixed period of 7 days between the day of drug administration of the first period (Period 1 Day 1) and the day of drug administration of the second period (Period 2 Day 1, being Day 8 of the entire study). You will stay in the clinical research centre in Zuidlaren from the morning 3 days before drug administration in the first period (morning of Day -3) up to 3 days after drug administration in the second period (Period 2 Day 4, being Day 11 of the entire study). Thus, you will stay in the clinical research centre for 14 days (13 nights).

Intervention

1 single dose of Vitamin D3 with cyclodextrine on Day 1 or 8 and 1 single dose of Vitamin D3 without cyclodextrine on Day 1 or 8

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

There is no general consensus on the maximum safe daily dose of vitamin D3, but generally in the Netherlands a dose of 50 micrograms per day is assumed to be the safe maximum. This is twice the amount that will be given on each day of study drug administration in this study.
The risk that these two administrations can cause signs of overdosing is very small.

The side effects reported with the intake of Vitamin D3 include:
- Uncommon side effects (affecting less than 1 in 100 people): too much calcium in your blood (hypercalcaemia), you may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion, too much calcium in your urine (hypercalciuria).
- Rare side effects (affecting less than 1 in 1000 people): skin rash, itching, hives.

With the doses used in this study no serious adverse effects are expected. The occurrence of known or other effects cannot be excluded. All drugs cause

adverse events to some extent.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy male and female subjects
18-65 yrs, inclusive
BMI: 18.5-30 kg/m2, inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another

drug study within 60 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-01-2013
Enrollment:	54
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nvt
Generic name:	Cyclodextrin with vitamin D3
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Vitamin D3
Generic name:	cholecalciferol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	10-01-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-01-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-005724-14-NL
CCMO	NL43064.056.12