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Patient preference and acceptability of calcium plus vitamin D3 supplementation: a randomised, open, cross-over trial

Submission date
24/04/2008

Recruitment status
No longer recruiting

Registration date
09/06/2008

Overall study status
Completed

Last Edited
12/04/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CW-004-IN

Study information

Scientific Title
Patient preference and acceptability of calcium plus vitamin D3 supplementation: a randomised, open, cross-over trial

Study objectives
The aim of this trial was to assess the preference for a formulation based on the identification of some of the factors that may influence compliance with the intake of calcium plus vitamin D3 supplements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Local Ethical Committee in February 2003.

Study design
Randomised, open, cross-over clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteoporosis

Interventions
The Calci-Chew D3 chewable tablets (Nycomed, Denmark) contained 1250 mg of calcium carbonate (equivalent to 500 mg elemental calcium) and 400 IU of cholecalciferol (equivalent to 10 µg vitamin D3). The sachet of calcium plus vitamin D3 (Cad, Will-Pharma) contained 1250 mg of calcium carbonate (equivalent to 500 mg elemental calcium) and 440 IU of vitamin D3.

The patients received both trial medications for 14 days, which was considered adequate for a patient to become familiar with the formulation and to assess the preference and acceptability. The patients received either the chewable tablet for two weeks followed by the sachet for two weeks or vice versa.

Total duration follow-up: 28 weeks

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Calcium, vitamin D3 supplementation

Primary outcome measure
To assess any preference between Calci-Chew D3 and Cad, measured at visit 3 (day 28).

Secondary outcome measures
1. To compare acceptability of the formulations using an 11-point rating scale, measured at visit 2 (day 14) and visit 3 (day 28)
2. To record tolerability and adverse events, measured at visit 2 (day 14) and visit 3 (day 28)

Overall study start date
01/02/2003

Completion date
30/11/2003

Eligibility

Key inclusion criteria
1. Patients with osteoporosis who required calcium and vitamin D supplementation as part of their anti-osteoporotic therapy
2. Age range: greater than 18 years, gender: women and men

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
102

Key exclusion criteria

1. Use of the trial medications during the past six months
2. Any condition for which the trial medications are contra-indicated, such as hypercalcaemia, hypercalciuria, Zollinger-Ellison syndrome, and nephrolithiasis
3. Use of drugs known to interact with the trial medications (e.g., digoxin, tetracycline, fluoroquinolones, bisphosphonates, iron, sodium fluoride, diuretics, phenytoin, barbiturates, corticosteroids, levothyroxine, ion exchange resins, laxatives)
4. Planned surgery during the four-week study period
5. Pregnant, possibly pregnant, or breastfeeding women

Date of first enrolment
01/02/2003

Date of final enrolment
30/11/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije University Medical Centre
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
Nycomed (Denmark)

Sponsor details
Langebjerg 1
Roskilde
Denmark
DK-4000
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Info@nycomed.com

Sponsor type
Industry

Website
http://www.nycomed.com/en/menu/

ROR
https://ror.org/03bsswy66

Funder(s)

Funder type
Industry

Funder Name
Nycomed (Denmark)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2010	30/12/2020	Yes	No