ISRCTN72183044 https://doi.org/10.1186/ISRCTN72183044

A randomised double-blind parallel-group study evaluating effcacy and safety on MEGA tablets compared to Kalcipos® tablets in adult subjects

Submission date
01/06/2007

Recruitment status
No longer recruiting

Registration date
19/09/2007

Overall study status
Completed

Last Edited
19/09/2007

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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CT06-MEGA-001

Study information

Scientific Title

Acronym
MEGA

Study objectives
The treatment to be tried will result in recommended levels of serum 25-hydroxy-vitamin D.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Regionala Etikprovningsnamnden i Linkoping, Sweden (one of six regional ethical boards in Sweden) on the 11th October 2006 (ref: Dnr M150-06 [EudraCT-nr: 2006-002595-17]).

Study design
A prospective randomised double-blind parallel group study evaluating efficacy and safety of a one year treatment.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild or moderate vitamin D deficiency

Interventions
Supplementation with either calcium and vitamin D or calcium alone. The subjects will be treated with two tablets per day for twelve months. The allocation of subjects to treatment, study product (vitamin D and calcium) or reference product (calcium), will be done by randomisation at start of the study.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Kalcipos®, vitamin D

Primary outcome(s)
Serum levels of 25-hydroxyvitamin D, measured at baseline, 3, 6, 9 and 12 months.

Key secondary outcome(s))

1. Serum levels of parathyroid hormone and biochemical bone markers, measured at baseline, 6 and 12 months
2. Safety, measured at baseline, 3, 6, 9 and 12 months

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Men and women 55 to 85 years of age
2. Mild or moderate vitamin D insufficiency (serum 25-hydroxy-vitamin D 10-70 nmol/L)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Subjects with severe vitamin D deficiency (serum 25-hydroxy-vitamin D below 10 nmol/L)
2. Suspected osteomalacia
3. Serious diseases or drug treatments that may interfere with study results

Date of first enrolment
05/01/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Endocrinology
Linköping
Sweden
S-58185

Sponsor information

Organisation
Recip AB (Sweden)

ROR
https://ror.org/01apnjb23

Funder(s)

Funder type
Industry

Funder Name
Recip AB (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration