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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

Contact name
Dr Goran Toss

Contact details
Department of Endocrinology
EM-kliniken
University Hospital
Linköping
Sweden
S-58185
+46 (0)13 222 000
Goran.Toss@lio.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
Serum levels of 25-hydroxyvitamin D, measured at baseline, 3, 6, 9 and 12 months.

Secondary outcome measures
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

Overall study start date
05/01/2007

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

Age group
Senior

Sex
Both

Target number of participants
56

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)

Sponsor details
Lagervagen 7
Haninge
Sweden
S-13650

Sponsor type
Industry

Website
http://www.recip.se/

ROR
https://ror.org/01apnjb23

Funder(s)

Funder type
Industry

Funder Name
Recip AB (Sweden)

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