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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
01/06/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
19/09/2007	Completed	Results
Last Edited	Condition category	Individual participant data
19/09/2007	Nutritional, Metabolic, Endocrine	<ul><li>Record updated in last year</li></ul>

# 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

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

Αll

## 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