

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

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| <b>Submission date</b><br>01/06/2007   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>19/09/2007 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>19/09/2007       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input type="checkbox"/> Results                     |
|  |  | <input type="checkbox"/> Individual participant data |
|  |  | <input type="checkbox"/> 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

# 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 Linköping, 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