

Vitamin D deficiency among non western immigrants: treatment with vitamin D supplementation or sunlight?

Submission date 19/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 19/12/2005	Overall study status Completed	☐ Protocol
Last Edited 24/08/2009	Condition category Nutritional, Metabolic, Endocrine	☐ 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
NTR350; METC 2003-202

Study information

Scientific Title

Study objectives

Supplementation of vitamin D3 (daily 800 IU or 3 monthly 100,000 IU) has the same effect on muscle complaints and weakness among non western immigrants as daily UV light exposure (sunlight).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Multicentre randomised open label active controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Vitamin D deficiency, Muscle weakness

Interventions

Time period: 6 months

1. Sunlight exposure: April until Sept
2. 3 monthly supplementation of vitamin D3 - 100,000 IU, VU University Medical Center
3. Daily supplementation of vitamin D3 - 800 IU, Lommerse Pharma

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Muscle strength and mobility (Takei TTK 5001, Hoggan MicroFEt, Chairtest). Measurement: baseline and after 3, 6 and 12 months
2. 25-OH Vitamin D, PTH: baseline and after 3, 6, 12 months
3. Phosphate, Alkaline phosphatase, Albumin, Creatinine, Glucose Hb, Ht: baseline and after 6 months

Key secondary outcome(s)

Sunlight exposure, diet, use of medicine intake, questionnaires: baseline and after 3, 6, 12 months.

Completion date

01/06/2006

Eligibility

Key inclusion criteria

1. 25-OH Vitamin D <25 nmol/l
2. Age during study: 18-65 years
3. Non-western immigrants

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Key exclusion criteria

1. No complaints or symptoms
2. No diseases which are interfering with measurement (e.g. psychoses, arthritis of the knee or hip)

Date of first enrolment

15/03/2004

Date of final enrolment

01/06/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

VU University Medical Center

Amsterdam

Netherlands

1081 BT

Sponsor information

Organisation

VU University Medical Centre (Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration