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

Submission date	Recruitment status	[ ] Prospectively registered
19/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/08/2009	Nutritional, Metabolic, Endocrine	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Multicentre randomised open label active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
1. Muscle strength and mobility (Takei TKK 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

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

Overall study start date
15/03/2004

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
210

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)

Sponsor details
EMGO-Institute and Department of Public and Occupational Health
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Sponsor type
Not defined

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

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