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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26009

Source
NTR

Brief title
N/A

Sponsors and support

Primary sponsor: VU University medical center
EMGO Institute
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. Muscle strength and Mobility (Takei TKK 5001, Hoggan MicroFEt, Chairtest). Measurement: baseline and after 3, 6 and 12 months;

2. 25(OH)D, PTH: baseline and after 3,6,12 months;

3. Fosfate, Alkalische fosfatse, Albumin, Creatinine, Glucose Hb, Ht: baseline and after 6

months.

Secondary outcome

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

Study description

Background summary

The aim of this study is to determine if the efficacy is the same for supplementation of vitamin D3 (daily 800IU or 3 monthly 100.000IU) and sunlight exposure on serum 25(OH)D levels, muscle strength and complaints. Non western immigrants with serum 25(OH)D < 25 nmol/l receive treatment during 6 months and are followed for another 6 months. RCT is used as study design.

Study objective

Supplementation of vitamin D3 (daily 800IU or 3 monthly 100.000IU) has the same effect on muscle complaints and weakness among non western immigrants as daily UVlight exposure (sunlight).

Study design

N/A

Intervention

Time period: 6 months.

1. Sunlight exposure: April till 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.

Contacts

Public
VU University Medical Center, EMGO-Institute - LASA,

Van der Boechorststraat 7
Ilse Wicherts
Van der Boechorststraat 7
Amsterdam 1081 BT
The Netherlands
+31 (0)20 4449336
Scientific
VU University Medical Center, EMGO-Institute - LASA,
Van der Boechorststraat 7
Ilse Wicherts
Van der Boechorststraat 7
Amsterdam 1081 BT
The Netherlands
+31 (0)20 4449336

Eligibility criteria

Inclusion criteria

1. 25(OH)D < 25 nmol/l;

2. Age during study: 18-65 yrs;

3. Non-westerse immigrants.

Exclusion criteria

1. No complaints or symptoms;

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2004
Enrollment:	210
Type:	Actual

Ethics review

Positive opinion

Date:	20-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL312
NTR-old	NTR350
Other	: METC 2003-202
ISRCTN	ISRCTN58849315

Study results

Summary results
N/A