

The effect of vitamin D-supplementation on insulin sensitivity in non-western immigrants in the Netherlands

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To assess whether supplementation of vitamin D3 (1200 IU/day) in vitamin-D deficient non-western immigrants at risk for type 2 diabetes mellitus can improve the insulin resistance and betacell function as well.

Ethical review	Approved WMO
Status	Completed
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON32789

Source

ToetsingOnline

Brief title

Vitamin D-supplementation and insulin sensitivity in non-western immigrants

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Vitamin related disorders

Synonym

human metabolism of sugar, insulin sensitivity

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: immigrants, insulin sensitivity, vitamin-D deficiency

Outcome measures

Primary outcome

Primary outcome are the incremental Area Under the Curve (AUC) of glucose of insulin after a 75 g oral glucose tolerance test (OGTT).

Secondary outcome

Secondary outcome measures are fasting serum lipids, BMI and physical performance.

Study description

Background summary

Both type 2 diabetes mellitus and vitamin D deficiency have a high prevalence rate in non-western immigrants. A 50% prevalence of vitamin D deficiency, defined as serum 25-hydroxyvitamin D < 25nmol/l, was found in Turkish and Moroccan immigrants in the Netherlands.

Beside the well known effects of vitamin D on calcium and bone homeostasis vitamin D exerts important physiological effects on muscle strength, physical performance and the immune system. Moreover, vitamin D appears to enhance insulin secretion and insulin sensitivity. As a consequence, treatment of vitamin D deficiency in non-western immigrants at risk for diabetes could contribute to the prevention of type 2 diabetes mellitus.

Study objective

To assess whether supplementation of vitamin D3 (1200 IU/day) in vitamin-D deficient non-western immigrants at risk for type 2 diabetes mellitus can improve the insulin resistance and betacell function as well.

Study design

The study is designed as a randomised double blind, placebo-controlled trial, with an intervention and a control group It will last for 4 months. At 0 and 4

months an oral glucose tolerance test will be performed.

Intervention

The intervention group (1) will receive vitamin D3 1200 IU/day in addition to calcium 500mg (2); the control group will receive calcium 500mg only.

Study burden and risks

The visits to the hospital and the oral glucose tolerance tests may cause some discomfort to the subjects, however this is only at a limited degree. The oral glucose tolerance test is a common test at the polyclinics. The medication has to be taken due to the vitamin D deficiency.

Contacts

Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
NL

Scientific

Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

vitamin D deficiency, impaired fasting or at random bloodglucose

Exclusion criteria

serious illness, diabetes mellitus, severe vitamin D deficiency, concurrent medication that may interfere with the interpretation of the data of the study, serious mental impairment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	24-08-2009
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO	
Date:	06-02-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL25585.029.08