The effect of vitamin D-supplementation on glucose metabolism in non-western immigrants in the Netherlands.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26914

Source
Nationaal Trial Register

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

Health condition

Vitamin D deficiency, insulin resistence, non-western immigrants, prevention of type 2 diabetes mellitus .

Sponsors and support

Primary sponsor: VUmc (funding ZonMw)
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

What is the effect of vitamin D supplementation on insulin sensitivity parameters derived from the OGTT in non-western immigrants at risk for diabetes mellitus?

Secondary outcome

1. What is the effect of vitamin D supplementation on glucosemetabolism, BMI, physical performance and lipid profiles in non-western immigrants at risk for diabetes mellitus?

2. What is the compliance with the study medication?

Study description

Background summary

In this randomised controlled trial we study the effect of moderately high dose vitamin D supplemtation on insulin sensitivity, glucose metabolism, vascular function and physical performance in non western immigrants at risk for type 2 diabetes mellitus in the Netherlands.

Study objective

A moderately high vitamin D3 supplementation will improve pre-diabetes parameters in non-western immigrants with a vitamin D deficiency and obesity.

Study design

1. 0,2 and 4 months;

2. OGTT;

3. Physical performance test;

4. LASA-score;

5. Vascular functiontest;

6. Bloodtest.

Intervention

4 months vitamin D 1200 IE/calcium 500 mg once daily, vs 4 months placebo/calcium 500 mg once daily.

Contacts

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Eligibility criteria

Inclusion criteria

1. Written informed consent;

2. Non-western immigrants, male and female;

3. Aged between 20 and 65 years;

4. A body mass index (BMI) above 27(kg/m2);

5. Vitamin D deficiency and insufficiency;

6. An impaired fasting glucose and/or an impaired random serum glucose;

7. Ability to comply with all study requirements.

Exclusion criteria

1. Pregnant or lactating women, or subjects who intend to become pregnant within the study period;

2. Severe vitamin D deficiency;

3. A history of type 1 diabetes mellitus, secondary diabetes mellitus, acute diabetic complications;

4. Concurrent medication that may interfere with the interpretation of the data of the study;

5. Badly controlled thyroid and/or adrenal disease;

6. Serious physical impairment;

7. Serious diseases;

8. Serious mental impairment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2009
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion
Date: 20-05-2009
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	NL1717
NTR-old	NTR1827
Other	MEC VUMC : 2008/270
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A