Vitamin K and arterial calcification

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25255

Source
Nationaal Trial Register

Brief title
Vitacal

Health condition

Vitamin K, menaquinone-7, arterial calcification, dp-ucMGP, diabetes patiënts, arterial stiffness, bone metabolism.

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Dutch Heart Foundation

Intervention

Outcome measures

Primary outcome

Arterial calcifications as quantified by 18F-NaF PET/CT imaging.

Secondary outcome

- Arterial calcification in other arteries than the femoral artery as quantified by 18F-NaF PET/CT imaging.

- Bone metabolism in the lumbar spine, as quantified by 18F-NaF PET/CT imaging.

- Arterial stiffness, as quantified by pulse wave velocity measurement.

- Dpuc-MGP, as quantified using a sandwich ELISA.

Study description

Study objective

We expect that supplementation with vitamin K will attenuated or reduce ongoing calcification and will significantly reduce dp-ucMGP in patients with type 2 diabetes.

Intervention

vitamin K2 (menaquinone-7)

Contacts

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Eligibility criteria

Inclusion criteria

- Middle aged men and women ¡Ý 40 years.

- Diagnosed with type 2 diabetes.

- At high risk of arterial calcification, based on an Ankle Brachial Index (ABI) <0.9 or ¡Ý 1.3 or diagnosed PAD (prevalence is 24% in patients with type 2 diabetes (39)).

- Written informed consent

Exclusion criteria

- Contra-indication for undergoing 18F-NaF PET/CT scan (pregnancy, breastfeeding, recent radiotherapy or chemotherapy).

- Subject underwent amputation.

- Not willing to give up blood donation during the study.

- Using vitamin K antagonists.

- Known coagulation problems (history of thrombosis).

- Using vitamin supplements that contain vitamin K, vitamin D or calcium.

- A mean vitamin K2 intake ¡Ý 120 ¦Ìg/day measured with a telephone questionnaire.

- Natto or goose liver consumers.

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-10-2015
Enrollment:	0
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 45148
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5147
NTR-old	NTR5287
CCMO	NL53572.041.15
OMON	NL-OMON45148

Study results