Placebo-controlled double-blind randomized controlled trial investigating vitamin K supplementation on vascular calcification propensity in vitamin K deficient renal transplant recipients

Published: 24-03-2020
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To study the effect of vitamin K supplementation on calcification propensity and vitamin K status in RTRs with vitamin K deficiency.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Vitamin related disorders
Study type	Interventional

Summary

ID

NL-OMON49950

Source
ToetsingOnline

Brief title
NTx-vitK

Condition

- Vitamin related disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
vascular calcification propensity

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: nederlandse nierstichting

Intervention

Keyword: renal transplant recipients, vascular calcification, vitamin K

Outcome measures

Primary outcome

Primary endpoint is change from baseline to end of intervention (12 weeks) in serum calcification propensity.

Secondary outcome

Secondary endpoints include change from baseline to end of intervention (12 weeks) in parameters of vitamin K status (e.g., dp-ucMGP) and vascular stiffness (i.e., pulse wave velocity).

Study description

Background summary

Vascular vitamin K deficiency is prevalent among renal transplant recipients (RTRs) and is associated with an increased risk of cardiovascular disease. Restoring vitamin K status in RTRs is postulated to be associated with improvement of calcification propensity.

Study objective

To study the effect of vitamin K supplementation on calcification propensity and vitamin K status in RTRs with vitamin K deficiency.

Study design

Investigator-initiated, mono-center, double-blind, placebo-controlled randomized clinical trial (12 weeks, 2 arms: vitamin K2 MK-7 vs. placebo).

Intervention

Capsules containing the dietary supplement vitamin K2 menaquinon-7 (2x180 *g; 360 *g/day) or placebo.

Study burden and risks

The study includes two study visits which include blood sampling, 24-hour urine collection, and measurements of blood pressure and pulse wave velocity. These procedures are all routine clinical measurements and safe. Patients may experience a pill-burden (2 capsules/day). Multiple clinical studies indicate that vitamin K2 supplementation in the proposed doses is safe and does not cause hypercoagulation. Furthermore, WHO has set no upper tolerance level for vitamin K intake.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Age *18 years
2. Male and female renal transplant recipients
3. Participant of TransplantLines
4. Vitamin K deficient; dp-ucMGP >500 pmol/L
5. eGFR > 20 ml/min/1.73m2
6. Signed informed consent

Exclusion criteria

1. Treatment with vitamin K antagonists or direct oral anticoagulants (DOAC)
2. Atrial fibrillation
3. Known coagulopathy
4. Active malignancy; exception treated basal cell or squamous cell carcinoma
5. Current or planned pregnancy or lactation
6. Known intestinal malabsorption

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	vitamin K2 MK-7
Generic name:	vitamin K2 MK-7

Ethics review

Approved WMO Date:	24-03-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-04-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2019-004906-88-NL
CCMO	NL69395.042.20
Other	Trial NL7687