A randomized study on probiotics and their effect on vitamin K2 status

Published: 26-06-2020 Last updated: 10-04-2024

To investigate the effect of probiotics for 12 weeks on vitamin K status vs placebo.

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Other condition **Study type** Interventional

Summary

ID

NL-OMON55095

Source

ToetsingOnline

Brief title

PROVITAK

Condition

- Other condition
- Vitamin related disorders

Synonym

nutritional status, vitamin K status

Health condition

vitamine K status

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Health Holland, Winclove B.V.

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Intervention

Keyword: matrix gla protein, probiotics, vitamin K, vitamin K dependent proteins

Outcome measures

Primary outcome

vitamin K status - measured as dephosphorylated uncarboxylated matrix gla protein.

Secondary outcome

vitamin K metabolites in urine and stool

Study description

Background summary

Healthy gut bacteria are also known as probiotics and stimulate gut health and help the immune system. Vitamin K status is the average of vitamin K for a longer period. Certain probiotics can produce vitamin K. Vitamin K is essential for the activation of certain proteins. These proteins are involved in vascular health to halt vascular calcification. Vascular calcification is a strong risk factor for cardiovascular disease. At this moment, there is no effective intervention to halt vascular calcification. Vitamin K can be a novel solution.

Study objective

To investigate the effect of probiotics for 12 weeks on vitamin K status vs placebo.

Study design

Randomized-controlled double blind study

Intervention

To eat the content of 1 sachet of probiotics mixed with a cup of yoghurt or custard for 12 weeks. Everyday 1 sachet will be used.

Study burden and risks

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Participation to this study is completely voluntary. Study participants will be requested to use 1 sachet of probiotics daily for 12 weeks. The probiotics should be mixed with a cup of yoghurt or custard and the mixture should be eaten. The participants will be asked to go to the research center for 4 times. The first visit is the screening to check if participants are eligible. For the other 3 visits participants will be asked to bring 24-hour urine and a stool sample. During these visits a blood sample will be drawn by means of venapuncture, during the screening visit blood will be drawn by means of a fingerprick.

The use of probiotics can cause a temporarily change in bowel movements, which will normally stabilize within 2 weeks. The blood drawn can cause a small bruise. All probiotic species are already on the market and available over the counter. To conclude, the risks for this study are minimal.

Contacts

Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117 Amsterdam 1081 HV NL

Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Higher cardiovascular risk without type 2 diabetes - at least 1 of the following risk factors:

- o systolic blood pressure > 140mm Hg, diastolic blood pressure > 90 mmHg or use of blood pressure lowering medication and/or
- o Non-fasting glucose >=7.8 and <11.1mmol/l.
- o Family history of cardiovascular disease < 65 years
- o Total cholesterol > 6.5 mmol/l or use of statins
- o Smokers >= 50 years
- o Estimated glomerular filtration rate > 30 and < 60 ml/min

Exclusion criteria

- Pregnancy, lactation or a female planning to conceive within the study period
- Any significant medical reason for exclusion as determined by the investigator
- Unable to give written informed consent
- Unable to speak, read and/or write Dutch
- Diabetes of any type.
- Age <50 or >75 years
- Body mass index < 20 or > 39 kg/m²
- Using vitamin supplements that contain vitamin K, or unwilling to stop
- Using probiotic supplements
- Natto or goose liver consumers
- Use of vitamin K antogonists such as warfarin, acenocoumarol or coumarin derivates
- Use of antibiotics
- Colectomy
- Crohn's disease/ colitis Ulcerosa
- Use of more than 3 alcoholic beverages per day

Study design

Design

Study phase: 2

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Double blinded (masking used)

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Control: Placebo

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 22-11-2021

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 26-06-2020

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 26-01-2021

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 30-09-2021

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 25-11-2021

Application type: Amendment

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 NL71758.029.19 Other NTR (TC = 7505)