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

Published: 26-06-2020
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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.

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

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

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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)

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)