The effect of plant stanol ester consumption on the vaccination response to a COVID-19 vaccine

Published: 18-03-2021
Last updated: 04-04-2024

The primary objective of this study is to demonstrate clinical benefits of consumption of plant stanols (delivered via products enriched with plant stanol esters) on the vaccination response to a COVID-19 vaccine in overweight or obese patients aged...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lipid metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON51220

Source
ToetsingOnline

Brief title
Plant stanol esters and COVID-19 vaccination response

Condition

- Lipid metabolism disorders

Synonym
obesity, Overweight

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Raisio Nutrition Ltd.

Intervention

Keyword: COVID-19 vaccination, Immune system, Overweight and obesity, Plant stanols

Outcome measures

Primary outcome

The main study endpoint is vaccination response to a COVID-19 vaccine.

Secondary outcome

Secondary endpoints include amongst others hematological, inflammatory and immunological parameters (e.g. hs-CRP, leukocyte differential count) and metabolic markers (e.g. blood lipid profiles, plasma glucose, serum insulin, HOMA-IR).

Study description

Background summary

Plant stanols are known to lower low-density lipoprotein cholesterol (LDL-C). However, studies have suggested that these compounds also beneficially influence the immune system, e.g. increasing vaccine-specific antibody titers. BMI and age have previously been negatively associated to vaccination responses. These results are very relevant in light of the current COVID-19 pandemic. If plant stanols indeed have beneficial effect on the immune system, people with overweight or obesity and higher age might benefit from consuming plant stanols prior to receiving the COVID-19 vaccination. We here decided to focus on subjects with overweight or obesity.

Study objective

The primary objective of this study is to demonstrate clinical benefits of consumption of plant stanols (delivered via products enriched with plant stanol esters) on the vaccination response to a COVID-19 vaccine in overweight or obese patients aged 18 years or older.

Study design

A double-blind, randomized, placebo-controlled trial will be carried out. The

intervention period lasts at least 6 weeks.

Intervention

The intervention group will receive mini drinks (100 mL) containing 2g plant stanols each (present as plant stanol esters esterified to rapeseed oil) and are required to take two drinks daily in order to reach a required dose of 4g plant stanols per day. The control group will receive control mini drinks containing rapeseed oil without plant stanols esterified to it and are also required to take two drinks per day. Both drinks are oat-milk based and blueberry flavored.

Study burden and risks

Subjects will be screened via telephone to determine eligibility. If a subject fulfills all criteria, a baseline visit is planned where the informed consent is obtained at the start. If the consent form is signed, a baseline blood sample will be taken and subjects will start consuming the mini drinks until they receive an official invitation from the government to make an appointment for their the COVID-19 vaccination. This means that the time period between the start of consuming the stanol ester enriched products and the actual vaccination might differ between participants, but the minimal period for consumption of the drinks is 2 weeks prior to the receiving the vaccination. People that receive their vaccination in the first two weeks of the study will be excluded from the study. We ask the volunteers to visit the university for a blood sample the day before the vaccination. Following the COVID-19 vaccination, participants will continue to consume the mini drinks and will visit the study site weekly for blood sampling for 4 weeks. There are no direct benefits for study subjects. The intervention and control mini drinks are considered to be safe. The study team is not involved in the vaccinations as such and we do not interfere with the official routes of vaccination planning by the government. Some study subjects may report pain during venipuncture. Subjects that do not fully adhere to the study protocol will be excluded from analyses and a per protocol analysis will be performed. Time investment will be approximately 3 hours in total. This estimation excludes travel time. The total blood sampling volume over the entire study period will be approximately 78 mL.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER

NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Men and women, 18 years or older, BMI 27-35 kg/m2, not using products with added plant sterols or plant stanols, willing to abstain from products with added plant sterols or plant stanols during study, willing to keep intake of fish oil and vitamin supplements constant during study

Exclusion criteria

Already received COVID-19 vaccination, already had a positive test for COVID-19 (all tests, e.g. PCR test or antibody test), allergy to an ingredient of the mini drinks, excessive alcohol use (>20 consumptions per week), regular use of drugs, blood donors that want to donate one month prior to or during the study, pregnant or breastfeeding women

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2021
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Comirnaty
Product type:	Medicine
Brand name:	COVID-19 Vaccine AstraZeneca
Product type:	Medicine
Brand name:	COVID-19 Vaccine Moderna

Ethics review

Approved WMO Date:	18-03-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-04-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2021-001080-24-NL
Other	Na METC goedkeuring wordt het in ClinicalTrials.gov geregistreerd
CCMO	NL76906.068.21