Effect of a vegetarian diet on innate immunity in patients with myocardial infarction and in healthy volunteers (FRESH-MI study)

Published: 13-11-2023
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To determine the effect of a five-week vegetarian diet on innate immunity of patients with a recent myocardial infarction and healthy participants.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON53267

Source
ToetsingOnline

Brief title
FRESH-MI study

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
heart attack, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Netherlands Heart Institute,HelloFresh

Intervention

Keyword: Inflammation, Innate immunity, Myocardial infarction, Vegetarian diet

Outcome measures

Primary outcome

The difference in cytokine production capacity of isolated peripheral blood mononuclear cells after ex-vivo stimulation before and after the vegetarian diet in group 2a AMI compared to the difference in cytokine production capacity before and after the no change diet in group 2b AMI.

Secondary outcome

- The cytokine production capacity of isolated peripheral blood mononuclear cells after ex-vivo stimulation before and after following a vegetarian diet in healthy participants (delta group 1 PAR and delta group 2 PAR).
- The cytokine production capacity of isolated peripheral blood mononuclear cells after ex-vivo stimulation after following a vegetarian diet compared to a no change diet in patients with a recent myocardial infarction (group 1 AMI versus group 2 AMI.
- The frequency of the consumption of vegetables per week at nine months follow-up.
- Systemic markers of inflammation (cytokines and chemokines)
- Leucocyte composition
- Phenotype of circulating monocytes on flow cytometry
- Lipid profile

Study description

Background summary

Inflammation plays a pivotal role in the development of atherosclerosis. Recent evidence suggests that plant-based diets may have favourable effects on inflammation. Inflammatory parameters such as total leucocytes, neutrophils and monocytes significantly reduce after starting a vegetarian diet. Also, plant based diet reduces the number of circulating monocytes. Based on these findings, we hypothesize that a vegetarian diet, compared to a habitual meat-rich diet, reduces the pro-inflammatory monocyte phenotype in patients with a recent myocardial infarction. If our hypothesis is proven, this provides alternative non-pharmacological therapeutical options in this high risk population.

Study objective

To determine the effect of a five-week vegetarian diet on innate immunity of patients with a recent myocardial infarction and healthy participants.

Study design

Prospective randomized open label blinded endpoint (PROBE) study.

Intervention

Study subjects will be randomly assigned to a vegetarian or their habitual (meat-rich) diet for five weeks. Then a stabilisation period of six weeks will follow. After that participants will follow the other dietary intervention for five weeks. A part of the participants will then start directly with the other dietary intervention and a part will start after five weeks. Blood will be drawn at given timepoints The frequency and time points at which blood samples will be taken, are different for each group. See figure 1 of the protocol. At baseline, at 12 weeks and at 9 months follow-up questionnaires will be taken.

Study burden and risks

There are no significant risks to subjects included in this dietary intervention study. Blood will be drawn during study visits, which will have negligible risk. Subjects might benefit because the intervention could have a positive impact on the primary and secondary prevention of myocardial infarction.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion criteria for patients:
- Age >= 18 years
- Acute myocardial infarction (STEMI/NSTEMI) with a clear culprit lesion on angiography and requiring primary PCI less than 1 week before randomisation
- Body mass index between 18.5 and 35 kg/m2
- Written informed consent

Inclusion criteria for healthy volunteers (life partners / spouses)
- Age >= 18 years
- Body mass index between 20 and 35 kg/m2
- Written informed consent

Exclusion criteria

Exclusion criteria for patients and healthy volunteers (life partners/spouses):
- Already on a vegetarian diet
- Previous myocardial infarction
- Diabetes Mellitus
- Medical history of any disease associated with immune deficiency (either congenital or acquired, including chemotherapy, chronic steroid use, organ transplant)
- Use of immunomodulatory drugs (e.g., NSAID, Prednisone)
- Vaccination less than one month before inclusion
- Clinically significant infections within 1 months prior to study entry (defined as fever >=38.5 degrees Celcius)
- Active malignant haematological disease
- Known eating disorder (e.g., Anorexia nervosa, Bulimia nervosa)

Exclusion criteria only for healthy volunteers (life partners / spouses):
- Use of lipid lowering therapy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-01-2024
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	13-11-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-03-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL84172.091.23