Effect of short-term time restricted eating on innate immunity in patients with coronary artery disease.

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To investigate the effect of short term TRE on the innate immune system in patients with a history of myocardial infarction.

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

Summary

ID

NL-OMON51605

Source
ToetsingOnline

Brief title
Time restricted eating and innate immunity / SIGNATURE study

Condition

- Coronary artery disorders

Synonym
Coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: De Nederlandse Hartstichting

Intervention

Keyword: Coronary artery disease, Innate immunity, Monocytes, Time restricted eating

Outcome measures

Primary outcome

- Cytokine production capacity of isolated peripheral blood mononuclear cells (PBMCs) after ex-vivo stimulation with relevant stimuli.

Secondary outcome

- Immune cell composition

- Circulating inflammatory markers

- Circulating metabolites

- Clinical cardiovascular risk factors: body weight, blood pressure, heart rate, BMI

- Cardiovascular risk factors in the blood:

o before start: renal function (creatinine), glucose, cholesterol (total, HDL-c, LDL-c, triglycerides), and lipoprotein(a), and uric acid measured via venous blood analysis

o Before and after the two diet interventions, we will measure glucose and cholesterol values.

- In a selection of subjects we will perform RNAsequencing and chromatin immunoprecipition to detect histone modifications.

- We will store plasma and serum in -80 C..

Study description

Background summary

Atherosclerotic cardiovascular diseases (CVD) are an important cause of morbidity and mortality. In the recent years, research has shown the prominent role of low grade systemic inflammation in CVD and the crucial role myeloid cells, mainly monocytes and macrophages, play in atherogenesis. The current treatment of atherosclerotic CVD is based on lifestyle changes and pharmacological treatment. However, many optimally treated patients remain suffering from recurrent events, which seems to be primarily driven by inflammation.

Lifestyle and diet interventions have become more important in the treatment and prevention of CVD. Time restricted eating (TRE), i.e. eating the normal amount of calories within a limited time period per day, has a beneficial effect on multiple factors involved in the development of CVD, such as blood pressure, heart rate, lipid and blood glucose levels, and insulin sensitivity. TRE also reduces markers of systemic inflammation and oxidative stress; markers that are involved in atherogenesis. Besides, short term TRE reduces the number of circulating monocytes.
Based on these findings, we hypothesize that TRE reduces the pro-inflammatory monocyte phenotype of patients with a history of myocardial infarction. Proof of this hypothesis will have clinical implications and helps creating more treatment options for patients with CVD.

Study objective

To investigate the effect of short term TRE on the innate immune system in patients with a history of myocardial infarction.

Study design

Exploratory prospective randomised open label blinded endpoint (PROBE) cross over study.

Participants will be randomised to a 2 week TRF period or a 2 week period in which they consume their regular diet within an unrestricted time period. Participants will be crossed over to the other treatment arm after a 6 weeks wash-out period. In the TRF-arm, participants have to consume their regular food intake during a 6 hour period (from 8:00 to 14:00), after which they start fasting for 18 hours. Blood will be drawn before and on the last day of both diet intervention periods

Intervention

Participants will be randomised to a 2 week TRE period or a 2 week period in which they consume their regular diet within an unrestricted time period.

Participants will be crossed over to the other treatment arm after a 6 weeks wash-out period. In the TRE-arm, participants have to consume their regular food intake during a 6 hour period (from 8:00 to 14:00), after which they start fasting for 18 hours. During this fasting period, the participants are only allowed to drink water. They will be helped by a dietician.

Blood will be drawn before and on the last day of both diet intervention periods.

Study burden and risks

There will be no risk. The participation will only include venous blood drawing and a diet intervention.

The burden associated with participation:
- Subjects must adhere to fixed times of eating and fasting.
- Test subjects may be bothered by the measurements during the study. For example, taking a blood sample may cause some pain or bruising.
- Participating in the study will cost extra time.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6225 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6225 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Adult (age >18 years)
- Diagnosed with a myocardial infarction (1 to 5 years ago diagnosed)
- Body mass index between 20 and 35 kg/m2
- Able to understand, be motivated and follow the study related procedures
- Able to understand and give written informed consent

Exclusion criteria

- Myocardial infarction (defined as an increase in cardiac enzymes in combination with symptoms of ischemia or newly developed ischemic ECG changes) in the year prior to screening.
- Coronary artery bypass graft surgery or other major (cardiovascular) surgery, stroke or transient ischemic attack (TIA) in the past 6 months days prior to screening.
- Use of immunomodulatory drugs
- Diabetes Mellitus type I and type II
- Medical history of any disease associated with immune deficiency (either congenital or acquired, including chemotherapy, active malignancy, organ transplant) or auto immune disease
- Clinically significant infections within 1 months prior to start of or during intervention period or control period (defined as fever >38.5).
- Vaccination <1 month before start of or during intervention or control period.
- Eating disorders

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-11-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	11-07-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-10-2022
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	NL80950.091.22