Trained immunity in bone marrow progenitors as driver of atherosclerosis in obesity.

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The goal is to get a better understanding about the role of innate immune cells and the development of ASCVD in obese subjects. We will look at the innate immune cells in blood and at the progenitor cells derived from the bonemarrow.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON49754

Source
ToetsingOnline

Brief title
TRIM in obesity

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Cardiovascular disease; obesity

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Nederlands Hart Stichting

Intervention

Keyword: Bone marrow, Cardiovascular disease, Inflammation, Obesity

Outcome measures

Primary outcome

The most important question is whether there is trained immunity in the bone marrow progenitor cells of the subjects with the metabolic syndrome compared to subjects without metabolic syndrome.

Secondary outcome

The two other study parameters are 1) whether there are characteristics of trained immunity in the circulating monocytes, and 2) whether there is heterogeneity in the circulating monocytes with respect to the trained phenotype.

Study description

Background summary

Obesity is a major risk factor for atherosclerotic cardiovascular disease (ASCVD), and it accounts for more than 2.5 million cardiovascular deaths each year. Some people with obesity develop metabolic complications, including the metabolic syndrome, a clustering of abdominal obesity, dyslipidaemia, glucose intolerance and hypertension; whereas other obese individuals remain metabolically healthy. The metabolic syndrome is an important risk factor for the development of ASCVD.

Previous research has shown that innate immune cells play an important role in ASCVD. With this study we want to investigate the role of progenitors of these innate immune cells in the bonemarrow in subjects mentioned below. We hope this will provide a better understanding in the development of ASCVD and possible novel therapeutics targets in the future.

Study objective

The goal is to get a better understanding about the role of innate immune cells and the development of ASCVD in obese subjects. We will look at the innate immune cells in blood and at the progenitor cells derived from the bonemarrow.

Study design

Observational single center study

Study burden and risks

There is no direct benefit to the study participants. The risks for participants are overall negligible, except for possible discomfort related to the venepuncture and one time bone marrow aspiration which will be performed by experienced personnel. After signing for informed consent, 10 ml blood will be drawn for the confirmation of difference in cytokine production capacity. Subsequently 50ml of blood will be drawn and 30ml of bone marrow aspirate. These procedures don*t impose a risk for the participants, other than a possible hematoma at the puncture site.

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

-Participant in 300OB cohort, so all have a BMI> 27 and age >18 years
-Males
-Written informed consent
-4 weeks prior to inclusion stop cholesterol lowering drugs such as: statins

Exclusion criteria

-Inability to personally provide written informed consent (e.g. for linguistic or mental reasons)
-Documented bleeding diathesis or thrombocytopenia <50 *10e9/L
-History of haematological malignant disease
-Current treatment for maligancy
-Acute or chronic infections at the time of participation
-Medical history of any disease associated with immune deficiency (either congenital or acquired, including chemotherapy, chronic steroid use, organ transplant)
-Clinically significant infections within 1 months prior to study entry (defined as fever >38.5)
-Previous vaccination within 1 months prior to study entry
-Chronic use of anti-inflammatory drugs such as NSAIDs (acetylsalicylic acid <100 mg/day excluded)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2020
Application type:	First submission
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	NL72484.091.20