

Systemic Mastocytosis and Cardiovascular Risk

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Our objective is to assess whether patients with SM compared to controls have more advanced atherosclerosis assessed by carotid intima-media thickness (C-IMT) and carotid plaques and have a more adverse cardiovascular risk profile.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON38215

Source

ToetsingOnline

Brief title

SMaCR

Condition

- Immune disorders NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

atherosclerosis, cardiovascular disease

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atherosclerosis, cardiovascular risk, systemic mastocytosis

Outcome measures

Primary outcome

The main study parameter is the extent of atherosclerosis determined by C-IMT and carotid plaques and presence of cardiovascular risk factors (hypertension, diabetes, dyslipidemia, overweight/obesity)

Secondary outcome

Not applicable

Study description

Background summary

Acute cardiovascular syndromes such as myocardial infarction and stroke are a major cause of death in Western society and are generally triggered by rupture of an atherosclerotic plaque¹. Inflammation, matrix degradation and lipid accumulation are generally considered key processes in atherosclerosis and the pathogenesis of plaque rupture². The mast cell, a prominent inflammatory cell type and a major effector cell in allergy and asthma, has been shown to accumulate both in the rupture-prone shoulder region of human atheromas^{3,4} and in the perivascular tissue (adventitia) during atherosclerotic lesion progression⁵⁻⁷. Because of the work in animal studies in which activated mast cells appeared to be causally associated to atherogenesis, we hypothesize that patients with SM have increased atherosclerosis and potentially an impaired lipid profile compared to controls.

Study objective

Our objective is to assess whether patients with SM compared to controls have more advanced atherosclerosis assessed by carotid intima-media thickness (C-IMT) and carotid plaques and have a more adverse cardiovascular risk profile.

Study design

The study design to be applied is a cross sectional study at the outpatient clinic of the department Immunology of the Erasmus MC.

Study burden and risks

The burden associated with participation is as follows: 1 site visit, a physical examination, 6 bloodsamples, 2 urine samples and a C-IMT measurement. The risks are small to negligible.

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

Age older than 18 years

Diagnosed with systemic mastocytosis according to WHO criteria
Given informed consent

Exclusion criteria

Age younger than 18 years
No informed consent

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO	
Date:	22-01-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL46896.078.13