Detection of Mast cells in Systemic Mastocytosis

Published: 17-11-2014 Last updated: 21-04-2024

We here wish to apply new advancements in multi-color flow cytometry for a detailed and sensitive examination of mast cells in peripheral blood of patients with SM.

Ethical review	Approved WMO
Status	Pending
Health condition type	Haematopoietic neoplasms (excl leukaemias and lymphomas)
Study type	Observational invasive

Summary

ID

NL-OMON44206

Source ToetsingOnline

Brief title DOMIS

Condition

• Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym Mast cell disorder

Research involving Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** Ministerie van OC&W,Sophia Kinderziekenhuis fonds

Intervention

Keyword: Flow cytometry, Mast cells, Mastocytosis, Peripheral blood

Outcome measures

Primary outcome

To study the reliable identification of mast cells in peripheral blood of

patients with systemic mastocytosis and investigate if numbers and/or phenotype

(expression of aberrant markers) differ from healthy controls.

Secondary outcome

To study numbers and phenotype of other leukocyte subsets (with an emphasis on

IgE+ B cells) in peripheral blood of patients with SM compared to healthy

controls.

Study description

Background summary

Systemic Mastocytosis (SM) is a disease characterized by the accumulation of mast cells in various tissues, mainly in the skin and in the bone marrow. Manifestations of the disease are largely provoked by the resultant increase in mast cell-derived mediators which have a variety of local and systemic effects. Diagnosis is based on a combination of major and minor criteria. In any case, investigation of the bone marrow (BM) is a hallmark in the diagnosis of SM, either for analysis of mutation status or flow cytometric identification of aberrant mast cells. Currently, detection of mast cells in peripheral blood has not been possible.

Study objective

We here wish to apply new advancements in multi-color flow cytometry for a detailed and sensitive examination of mast cells in peripheral blood of patients with SM.

Study design

Cross sectionel study at the outpatient clinic of the department of Immunology where at one time an extra tube of blood will be drawn from patients diagnosed with systemic mastocytosis.

Study burden and risks

There is a minimal burden for patients. Patients are already undergoing a venapunction for scheduled follow up different blood values, only an extra tube of blood needs to be drawn.

Contacts

Public Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80 Rotterdam 3015 CE NL **Scientific** Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80 Rotterdam 3015 CE NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Older than 18 years Diagnosed with systemic mastocytosis according to WHO criteria Informed written consent

Exclusion criteria

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:	Basic science

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2014
Enrollment:	80
Туре:	Anticipated

Ethics review

Approved WMO	
Date:	17-11-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

4 - Detection of Mast cells in Systemic Mastocytosis 13-05-2025

Date:	15-03-2016
Application type:	Amendment
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 CCMO **ID** NL49666.078.14