Immunophenotypic Profile of Peripheral Blood Mononuclear Cells and T cell Function in Sickle Cell Disease Patients.

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The characterization of the immunophenotypic profile of PBMC subsets in steady state SCD patients. The determination of general T cell function in SCD patients. Both will be used as reference profiles in further research evaluating immune...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haemoglobinopathies
Study type	Observational invasive

Summary

ID

NL-OMON54195

Source
ToetsingOnline

Brief title
Immunophenotypic profile of PBMCs and T cell function in SCD.

Condition

- Haemoglobinopathies

Synonym
hemoglobinopathy, Sickle cell disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Flowcytometry, PBMCs, Sickle cell disease, T cell function

Outcome measures

Primary outcome

The characterization of PBMC subsets in SCD patients with the HbSS/HbSß0 genotype as compared to matched healthy controls in order to elucidate potential perturbations in the adaptive immunity (PBMC subsets) in SCD.

Secondary outcome

The identification of differences between the immunophenotypic profile of PBMC subsets of adolescent SCD patients compared to matched healthy controls.

The identification of differences between the immunophenotypic profile of PBMC subsets of adult and adolescent HbSS/HbSß0 genotype SCD patients.

The determination of general T-cell effector function in steady state SCD patients in order to establish a reference that can be used in further research evaluation T-cell function after allogeneic SCT for SCD.

Study description

Background summary

Sickle cell disease (SCD) is increasingly being recognized as a pro-inflammatory condition associated with alterations in immune phenotype and function. These alterations probably contribute to high rates of graft failure after allogeneic stem cell transplantation (SCT) for SCD. The probability of graft rejection is generally higher in children and adolescents compared to the adult SCD population.
While impairments of innate immunity in SCD have been well described, a profound characterization of subsets of adaptive immune cells in steady state SCD patients is lacking. Extensive analysis of peripheral blood mononuclear cell (PBMC) subsets and measurement of general T cell effector function in

steady state SCD patients compared to matched healthy controls will provide an overview of the alterations of adaptive immune cells present in SCD.

Study objective

The characterization of the immunophenotypic profile of PBMC subsets in steady state SCD patients. The determination of general T cell function in SCD patients. Both will be used as reference profiles in further research evaluating immune reconstitution, graft rejection and T cell function after allogeneic SCT for SCD.

Study design

This is a cross-sectional laboratory study with a control group. A maximum of 50ml of blood will be drawn from all participants at one time point (T0).

Study burden and risks

For subjects included in this study no direct positive effect can be expected. The burden for participants will be limited to venipuncture and risks are not to be expected. This study will provide insight into the immunological alterations present in SCD patients compared to the healthy population. Findings of this study will be used as reference for further research involving SCD patients that undergo or underwent allogeneic SCT.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Inclusion criteria SCD patients
To be eligible to participate in this study, a subject must meet all the following criteria:
o Age 12 years or older
o High performance liquid chromatography (HPLC) confirmed diagnosis of HbSS/HbSß0
o Willing and able to provide written informed consent
o For children 12-16 years: additional written informed consent of parent/caretaker

Inclusion criteria healthy volunteers
To be eligible to participate in this study, a subject must meet all the following criteria:
o Age 18 years or older
o Willing and able to provide informed consent
o No self-reported medical issues that could interfere with immunity
o Originating (or parents originating) from region where SCD occurs

Exclusion criteria

Exclusion criteria SCD patients
A potential subject who meets any of the following criteria will be excluded from participation in this study:
o History of allogeneic SCT
o Participation in Amsterdam UMC SCT biobank because of planned allogeneic SCT
o History of chronic infection or autoimmune inflammatory disease
o Pregnancy, self-reported
o Vaso-occlusive disease in the preceding 4 weeks, self-reported
o Red blood cell transfusion in the preceding 3 months, self-reported

Exclusion criteria for healthy volunteers
A potential subject who meets any of the following criteria will be excluded from participation in this study:
o Carriership of sickle cell gene or other hemoglobinopathy, self-reported
o Chronic infection, self-reported
o Chronic auto-inflammatory disease, self-reported
o Use of chronic medication that affects the immune system, self-reported

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2022
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	31-01-2022
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam

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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	NL79404.018.21