Sickle Cell Outcome Research

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29491

Source
NTR

Brief title
SCORE

Health condition

Sickle cell disease

Sponsors and support

Primary sponsor: NA
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

1. To describe the natural course of disease e.g. symptoms and complications, growth, psychosocial and neurocognitive development, socioeconomic and demographic characteristics of children and adults with SCD;
2. To identify (molecular) genetic and epigenetic, biological, demographic and psychological and therapeutic determinants for morbidity, mortality and treatment outcome in children and adults with SCD;
3. To investigate the long-term effects of current and future therapies on symptoms and

complications, preservation of organ function, growth, psychosocial and neurocognitive development in children and adults with SCD;
4. To evaluate and improve aspects of health care organization and other (perceived) care aspects in children and adults with SCD by measurement of patient and treatment characteristics, patient-reported outcomes, patient reported experiences and to perform analyses of associations between these factors and health care outcome.

Secondary outcome

NA

Study description

Background summary

This long term retrospective and prospective observational cohort study in sickle cell disease (SCD) patients in the Netherlands aims to determine the natural history of SCD and to identify modifying factors which contribute to morbidity and mortality of the disease.

Study objective

More optimal prediction of SCD disease severity will lead to more precise management and treatment and development of novel therapeutic options.

Study design

Data will be collected retrospectively and prospectively at participants' half yearly regular clinic visits as part of standard care.

Intervention

NA

Contacts

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Ineke van Vliet

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Eligibility criteria

Inclusion criteria

- A diagnosis of SCD of any genotype;
- Written informed consent by the patient or legal guardians, and pediatric consent when indicated.

Exclusion criteria

- Any medical or social reason, which obstructs or inhibits study participation according to treating physician;
- Patient or legal guardians unable or unwilling to give consent, or lack of pediatric consent when indicated.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2019
Enrollment:	1000

Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7873
Other	METC Erasmus MC : MEC-2019-0436

Study results