Objective Neurocognitive assessment of young children with sickle cell disease by eye-tracking

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Red blood cell disorders
Study type	Observational invasive

Summary

ID

NL-OMON53538

Source
ToetsingOnline

Brief title
ONSET

Condition

- Red blood cell disorders
- Blood and lymphatic system disorders congenital

Synonym
sickle cell anemia, Sickle cell diseae

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: het Sikkelcelfonds

Intervention

Keyword: determinants, eye-tracking, neurocognitive development, sickle cell disease

Outcome measures

Primary outcome

Early identification of children with SCD at risk of impaired neurocognitive development. Eye-tracking will be performed to assess neurocognitive development.

Secondary outcome

To identify determinants (risk and protective factors) and biomarkers of early neurocognitive deficits in children with SCD, by looking at socio-economic status and biomarkers. Next to this, the relationship between early neurocognitive functioning and adaptive daily life functioning later in life will be analysed, by looking at the quality of life, the behavioural and emotional functioning and general development.

Study description

Background summary

Evidence indicates that Sickle Cell Disease threatens neurodevelopmental outcome. Previous research suggests that neurocognitive impairment is already present in toddlers. The future quality of life of children with SCD is highly dependent on their neurocognitive outcome, that is threatened by the course of their disease as well as the environment that they grow up in. It is important to identify as early as possible those individuals who are at the highest risk of neurocognitive impairment. This will enable early interventions to mitigate the detrimental effect of SCD on the developing brain. In order to develop such interventions, a deeper understanding of the underlying pathophysiological mechanisms is required.

Study objective

The main aim is to study early neurocognitive functioning and development in very young children with SCD. The secondary aims are to identify determinants (risk and protective factors) and biomarkers of early neurocognitive deficits in SCD and to analyse the relationship between early neurocognitive functioning and adaptive daily life functioning later in life (quality of life, behavioural and emotional functioning, general development)

Study design

Prospective observational study with an accelerated longitudinal design

Study burden and risks

There is no additional risk associated with participation in this study. The burden can be considered minimal. This study will assess the neurocognitive development of very young children with sickle cell disease. Therefore, this study can only be performed in this specific group of minors. The control group of healthy typical developing children will be used as a reference group for the SCD group and is necessary to elucidate the impact of SCD on the outcome measures, as corrected for age, sex, and socio-economic status. The available standardized population norms for some of the outcome measures do not include the demographic characteristics that can have a considerable influence on the neurocognitive development of a child [1]. As children with low socio-economic status are over-represented in the SCD population, the confounding influence of socio-economic status needs to be controlled, which cannot be done using the age-standardized population norm. Therefore, this study will need to include a demographically matched healthy, typically developing control group.
Blood drawings will be taken of children with sickle cell disease. As blood drawings are part of the patients normal procedure, blood collection will be combined with regular blood draws to reduce the burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

- Diagnosis of SCD (SCD group);
- Age 6 - 24 months old;
- Inhabitant of the Netherlands;
- Written informed consent from parent/caretaker;

Exclusion criteria

- Refused informed consent from parents/care-taker;
- Diagnosis of visual impairment;
- Diagnosis of a (co-morbid) congenital developmental condition
- Any neurological condition, unrelated to SCD, that could affect the central nervous system, such as brain trauma, epilepsy and meningitis/encephalitis.

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:	Recruiting
Start date (anticipated):	06-04-2023
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-08-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL82004.018.22