Beat the pain in Sickle Cell Disease

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

Summary

ID

NL-OMON55175

Source
ToetsingOnline

Brief title
BEATS

Condition

- Haemoglobinopathies

Synonym
sickle cell disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Private liefdadigheidsorganisatie (Rotary en ForWishdom)

Intervention

Keyword: Acute Chest Syndrome, Heart rate variability, Sickle cell disease, Vaso-occlusive

crisis

Outcome measures

Primary outcome

Primary study parameters:

- Heart related variables: resting heart rate, heartrate/steps-ratio

- Variables of Heart Rate variability (e.g. Standard deviation of the R-R

intervals = SDNN, RMDD, HF, LF/HF-ratio)

Primary oucomes:

A: Occurrence of Acute Chest Syndrome

B: Self-reported painful crises

Secondary outcome

• Length of stay (LOS)

• Need of (P)ICU admission

• Need of red blood cell transfusion

• Need of analgesic or opioids: maximum dose during hospital admission

Study description

Background summary

Sickle cell disease (SCD) is the most common inherited red blood cell disorder.
It is characterized by polymerization of hemoglobin S, resulting in the formation of rigid sickled-shaped red blood cells.
These cells can occlude the microvasculature causing hemolytic anemia, irreversible-organ damage and recurrent painful vaso-occlusive crises.
In its severe form, these crises require hospitalization for administration of

intravenous opioids. When patients are hospitalized for a painful crises, some may develop severe respiratory complications, called Acute Chest Syndrome (ACS). The clinical presentation of SCD is highly variable among patients and there are no adequate (bio)markers available. For this reason, this study is focused on the early prediction of ACS in admitted patients and the prediction of painful crises in ambulant patients. For the prediction, we will measure heart rate based variables (including heart rate variability) using the Apple Watch.

Study objective

The aim of this proof-of-concept study is to analyze the use of heart rate based variables using the Apple Watch:

A) To predict Acute Chest Syndrome in patients hospitalized patients for painful crises;
B) To predict painful crises in ambulant patients.

Study design

Patients with SCD from the age of 16 years old will be included in this study, divided over two study groups:

A) Hospitalized patients with painful crisis, longitudinal measurements
B) Ambulant patients, longitudinal measurements

Study burden and risks

The burden and the risks associated with participation in this study are low. Subjects will be asked to wear a wearable device on the wrist during the study period.
The additional burden for study participants in part B (ambulant patients to predict painful crises) is to keep a pain diary for the duration of six months.

The study is group-related, because SCD has a highly variable phenotype between patients and even within the same genotype. The variation is even greater if age is taken into account; children and adults are physiologically and pathophysiologically different from each other. Results obtained from one group cannot be extrapolated to the other group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Medical diagnosis of sickle cell disease
• Age from 16 years old
• Written informed consent.

Exclusion criteria

- Refused informed consent
- For heart rate based measurements: medical history of arrhythmias and chronic use of medication affecting the heart rate

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2021
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-02-2022
Application type:	First submission
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	NL74534.018.20