ISRCTN16126140 https://doi.org/10.1186/ISRCTN16126140

Patient benefits of a digital data platform for sickle cell disease

Submission date	Recruitment status	[X] Prospectively registered
07/09/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/09/2020	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/09/2024	Haematological Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Sickle cell disease (SCD) is a group of inherited health conditions that affect the red blood cells. The symptoms include painful episodes called sickle cell crises, which can be very severe and last up to a week. The current understanding of SCD's full natural history and the available treatment options for patients fall far behind that of many other diseases with a similar prevalence. Patient care is impacted by limitations around the data available to their clinicians outside of infrequent contacts with treatment centres, meaning the standard of care and speed at which it can be delivered is frequently lacking.
This study aims to find out whether a unified SCD digital data platform and wearable device improves patient experiences and outcomes through better monitoring of key metrics around pain crises and severe complications of the disease. These will be tracked through a combination of hospital and GP medical records, genetic information, as well as real-time data collected from the wearable devices.
By combining these into a complete digital patient profile, the aim is to provide patients and clinicians with better insight into the disease's natural history, which interventions have worked well to improve future treatment, and inform when a patient may be at risk of crises or severe end-organ pathologies. The work will study vital parameters collected over a long duration within a group of patients with SCD to determine how these relate to acute and chronic illnesses, as well as healthcare utilisation.

Who can participate?
1. Children with sickle cell disease aged 5-15, with consent from and attendance/guidance by parent or legal guardian
2. Adults with sickle cell disease aged 16 and over

What does the study involve?
No interventions or changes to medical treatment will be involved in the study, and all participants will follow the same study protocol.
The study will be conducted remotely, with patients participating in initial pre-study focus groups virtually over video call, in addition to a post-study focus group at the end of the study. The study of the technology will be ongoing, and participants will wear either their own or a study-provided smartwatch during their day-to-day lives, to track their vital parameters on a

constant and automated basis. These will include metrics such as heart rate and activity levels. The study will also involve the collation of each participant's hospital and medical GP records alongside this live wearables collected data, within the digital platform. The participant will need only provide informed consent for this, and the study team will manage the data requests and integration.

What are the possible benefits and risks of participating?
There are no direct benefits in terms of changes to treatment or other aspects of participants' care. The results will add to the current knowledge about SCD, potential triggers of pain crises or complications, and individual treatment options. It will provide participants with a greater understanding of their daily health and medical history, including information that they may choose to share with their clinical team to help manage their disease.
No interventions or changes to medical treatment are involved in the study, and the only potential risk will be data security. This has been securely addressed by the study team to ensure strong cybersecurity measures, encryption and two-factor authentication needed to access the digital platform.

Where is the study run from?
London North West University Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
July 2020 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Kim Summers, kim@saniushealth.com

Contact information

Type(s)
Public, Scientific

Contact name
Dr Kim Summers

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288780

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 288780

Study information

Scientific Title
Digital sickle cell – evaluating live evidence for vaso-occlusive crisis and end-organ damage intervention & prevention: benefits of implementing a unified digital sickle cell disease data platform, including real-time wearable device data, in disease management, patient experience, and clinical outcomes

Acronym
DiSC-ELEVEN

Study objectives
To determine the benefits of incorporating a unified digital data platform, in-depth digital patient profile and wearable device into standard care for sickle cell disease - collating historical patient data, a full genetic background, and live patient data - to real-world patient experiences and clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submission pending

Study design
Multicentre observational pilot/feasibility study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)

Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Sickle cell disease

Interventions
The study will be an observational trial, revolving around the use of a mobile app by participants in order to provide initial consent to participate and share their medical records with the study, key details, and link a wearable smartwatch.

The trial of the technology will be ongoing for 12 months, and participants will wear either their own or a study-provided smartwatch during their day-to-day lives, in order to track their vital parameters on a constant and automated basis. These will include metrics such as heart rate and activity levels.

The study will also involve the collation of each participant's hospital and medical GP records alongside this live wearables collected data, within the digital platform. The participant will need only provide informed consent for this, and the study team will manage the data requests and integration.

The digital data platform will unify information from multiple sources in order to provide a full patient profile that can be accessed by both patients and their clinicians. No further interventions will be involved, patients only required to wear their smartwatch on a daily basis in order for the device to collect key health metrics on an automated basis. The study will be conducted remotely, patients participating in initial pre-study focus groups virtually, over video call, in addition to a post-study focus group at the end of the trial.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mobile app and wearable smartwatch

Primary outcome measure
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 3 months
2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of the follow-up period at 13 months

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2020

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Children with sickle cell disease of any phenotype aged 5-15 years of age, with consent from and attendance/guidance by parent or legal guardian
2. Adults with sickle cell disease of any phenotype aged 16 years and over
3. Able and willing to sign written informed consent
4. Interest in participating in the study
5. Known history/diagnosis of sickle cell disease

Participant type(s)
Patient

Age group
Mixed

Lower age limit
5 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Incapacity to provide informed written consent
2. Known allergic reaction to any materials in wearable device

Date of first enrolment
01/12/2024

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London North West University Healthcare NHS Trust
Haematology and Sickle Cell Centre
Central Middlesex Hospital
Acton Lane
London
United Kingdom
NW10 7NS

Study participating centre
Barts Health NHS Trust
Pathology and Pharmacy Building
80 Newark Street
London
United Kingdom
E1 2ES

Sponsor information

Organisation
Eleven

Sponsor details
Level 39
One Canada Square
Canary Wharf
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Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal, as well as a patient-friendly report of key findings and insights at a de-identified level provided to study participants.

Intention to publish date
01/12/2026

Individual participant data (IPD) sharing plan
The researchers do not plan to share patient-level/raw data, as they anticipate some participants may wish to continue using the digital platform post-trial as part of their disease management. De-identified, cohort-level data will be made available upon request by clinicians, researchers who provide a methodologically sound proposal, or those developing novel therapeutic options who may require the real-world evidence base generated by the study. These proposals should be directed to Dr Kim Summers, kim@saniushealth.com, and will include a data access agreement. Links to the data will be provided upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V1	03/09/2020	08/10/2020	No	No