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A study to test the use of a visual tool in measuring disease activity in children with dermatomyositis

Submission date	Recruitment status	[X] Prospectively registered
09/02/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/02/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/08/2025	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Juvenile dermatomyositis (JDM) is a rare but serious disease which causes muscle and skin inflammation, affects blood vessels and can affect major organs. With treatment, the disease can enter remission, but course is unpredictable and persistent disease or disease flares occur. Blood vessel abnormality (vasculopathy) is key to disease pathogenesis and persistent vasculopathy is associated with more severe disease, worse disease manifestations, and risk of life-threatening complications. Blood vessels at the base of the fingernail can be visualised when magnified and provide a valuable insight into vascular disease activity. There is an unmet need to better evaluate vasculopathy in clinical practice, to improve long-term disease outcome. Nailfold capillary abnormalities have been found to relate to biomarkers of vascular disease activity in the blood stream of patients with JDM, but these vascular biomarkers are not yet available in routine clinical practice. The importance of measuring nailfold changes in clinic is well recognised but hampered by the lack of equipment that allows this to occur. Use of a handheld device, with images captured and sent to the specialist reporting centre can provide a step change in the management of patients with JDM.
This study will test the use of a visual tool (Dinolite CapillaryScope) that allows patients to see their blood vessels and help them know how active their disease is. If deemed useful it may provide an increased understanding of the need for medication need and motivation to improve adherence.

Who can participate?
Participants 0-18 years old, with juvenile dermatomyositis.

What does the study involve?
Participants will have nailfold capillaroscopy (NFC) performed on up to 8 fingers. Patients and parents will be asked to complete age-appropriate questionnaires on their opinions of NFC. Patients and parents will be invited to take part in an individual patient/family interview to further determine impact of NFC. This is optional. Healthcare professionals will complete a NFC data form at the time of NFC and time of receiving a report.

What are the possible benefits and risks of participating?
BENEFITS- If it is demonstrated that NFC is beneficial in clinic, it can easily and quickly be incorporated into all specialist centres that care for children/young people with JDM in the UK. If deemed useful, Dinolite CapillaryScope and NFC will provide an increased understanding of the need for medication need and motivation to improve adherence. It could help patients have a sense of control, reduce anxiety, give a better understanding of symptoms, sense of being understood, improve confidence in management and a more hopeful outlook for future quality of life/well-being.

RISKS- The main burden is the extra time taken in clinic for NFC to be performed on children /young people with JDM. This needs to be evaluated against any benefit for patients/parents and clinicians.
Nailfold capillaroscopy is painless and adverse events are not anticipated. It is possible that patients participating may reflect on implications of their disease, with emotional consequences. If patients experience any unexpected outcomes such as increased anxiety or emotional distress about their disease, they will be supported by our study psychologist and members of the multi-disciplinary team at each participating centre.

Where is the study run from?
Alder Hey Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2023 to February 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Liza McCann (Liza.McCann@alderhey.nhs.uk)
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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333838

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 60608, NIHR204944, IRAS 333838

Study information

Scientific Title
MYOSCOPE: Bringing a visual measure of disease activity into clinical practice to help children with dermatomyositis

Acronym
MYOSCOPE

Study objectives
The purpose of this study is to determine whether a low-cost handheld tool (Dinolite® CapillaryScope) can adequately capture blood vessel changes at the base of the fingernails in children/ young people with juvenile dermatomyositis (JDM) when it is used in clinic, and whether this benefits patients/parents in understanding their disease and need for medication, as well as benefiting healthcare professionals.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/02/2024, East Midlands – Nottingham 2 (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 20 7104 8057; nottingham2.rec@hra.nhs.uk), ref: 24/EM/0023

Study design
Interventional non-randomized with qualitative follow up

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Juvenile Dermatomyositis (JDM)

Interventions
Patients will be recruited from two UK centres. All patients wanting to participate in this study can do so. There is no randomisation. This study is predominantly cross-sectional.
During routine clinic visits, patients will have nailfold capillaroscopy (NFC) in up to 8 fingers (minimum 2 fingers), taking approximately 15 minutes. An age-adjusted questionnaire will explore feelings about NFC and if perceived to be helpful. Study participants will be invited to participate in a single individual/family interview to further explore impact of NFC. Options available will ensure families with digital poverty/language barriers can participate.
Clinicians will complete data at each patient visit (1-3 per patient) to document time taken for NFC, any difficulty, and whether NFC changed treatment decisions. After receiving a formal NFC report (within 1-2 weeks), clinicians will document if any further treatment changes were made. NFC will be compared to tools currently used to measure global and skin disease activity in JDM.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Feasibility of performing NFC in clinic and benefit (or not) to patients, parents and healthcare professionals. This will be assessed qualitatively through questionnaires and interviews.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Medical diagnosis of Juvenile dermatomyositis (JDM) with or without overlap features.
2. Less than 18 years of age
3. Any time point of disease.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Unwillingness to participate.
Procedures are in place to ensure that patients are not excluded due to language barriers, geographical location, digital poverty or other factors.
No patient / parent will be coerced into involvement of this research project. Patients can choose to leave the research project at any time, without the need to explain their reasons.

Date of first enrolment
26/06/2024

Date of final enrolment
13/03/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre

Great Ormond Street Hospital for Children
Great Ormond Street
London
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Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (Data will be collected on site and entered on to an electronic spreadsheet. The spreadsheet will be encrypted and be stored on a password protected computer in a locked area and the file will be password protected).

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes