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A multi-centre study testing a new imaging app to help diagnose systemic sclerosis using nailfold capillaroscopy

Submission date
11/11/2025

Recruitment status
No longer recruiting

Registration date
27/11/2025

Overall study status
Completed

Last Edited
30/12/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is testing a new software system called CapilyticsAcquisition, which helps healthcare professionals take and analyse images of the tiny blood vessels near the fingernails, a technique known as nailfold capillaroscopy. These images can help doctors assess conditions like Raynaud's phenomenon and systemic sclerosis (SSc).

The Capilytics system is designed to support non-specialist users in general rheumatology clinics by guiding them to collect high-quality images and automatically generating reports that may assist in diagnosis and treatment decisions.

The study aims to check that the CapilyticsAcquisition system works as intended, identify any risks or side effects, and gather feedback to refine the software and improve its usability.

Who can participate?
Participants in the study will include adults and children aged 6 and over who are being assessed for Raynaud's or SSc.

What does the study involve?
After giving consent, participants will complete a short questionnaire and have their nailfold capillaries imaged using the CapilyticsAcquisition system. This may happen during a regular clinic visit or a dedicated study appointment.

Once the images are taken, they will be securely uploaded to servers at The University of Manchester. The system will then automatically analyse the images and generate a clinical report. Before seeing the full report, the clinician will review a sample of the images and give their own assessment of the patient's condition and treatment plan. They will then view the full report and provide feedback on how useful it is.

After the imaging session, both participants and clinicians will complete questionnaires about their experience. Some participants and all healthcare professionals will also be invited to take part in interviews or group discussions to help improve the system.

What are the possible benefits and risks of participating?
Possible Benefits
Taking part in this study may help improve future care for people with Raynaud's phenomenon and SSc. By testing a new imaging and analysis system, the research could make it easier for hospitals to offer nailfold capillaroscopy and help doctors diagnose these conditions earlier and more accurately. While the report from the software will not affect the treatment of those taking part in the study, their participation will contribute to developing technology that could benefit others in the future.

Possible Risks
The procedure is very low risk and involves taking pictures of the small blood vessels at the base of the fingernails. Some participants may feel mild discomfort from keeping their hands still for a few minutes, and some people may feel anxious about being in a clinic or talking about their condition during interviews. The software report is for research only and will not be used to guide participants care in this study.

Where is the study run from?
University of Manchester, UK.

When is the study starting and how long is it expected to run for?
December 2025 to June 2026.

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

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
324900

Central Portfolio Management System (CPMS)
70207

National Institute for Health and Care Research (NIHR)
204551

Study information

Scientific Title
Automated capillaroscopy evaluation in Raynaud's and SSc (ACERS): Supporting early diagnostic decision-making in the general rheumatology clinic

Acronym
ACERS

Study objectives
The primary objectives of this study are:
- to verify that the Capilytics nailfold capillaroscopy image acquisition and reporting system performs as expected under normal conditions of use;
- to determine any undesirable side effects or risks under normal conditions of use;
- to assess whether any side-effects or risks are serious when weighed against the intended benefits of the device.
- Secondary objectives of this study are to collect questionnaire responses, conduct interviews (semi-structured and think-aloud) and focus groups with target users and patients to contribute

to the refinement of the software;
- to assess the usability of the software (target user feedback) and clinical reports.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/10/2025, West of Scotland REC 4 (Research Ethics – Room 29 2 nd Floor Administration Building Gartnavel Royal Hospital 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; +44 0141 314 4485/0213; ggc.wosrec4@nhs.scot), ref: 25/WS/0142

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Diagnostic

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Systemic sclerosis spectrum disorders

Interventions
This clinical investigation is a prospective, multi-centre study evaluating the Capilytics AI-based system developed for nailfold capillaroscopy image acquisition and analysis.

Following the consent process, participants will be asked to complete an anonymous equality, diversity and inclusion (EDI) questionnaire. We are collecting this data to ensure that, as Sponsor, we can further understand any specific barriers to research participation in our studies. With this additional information, we aim to address any potential issues to allow us to make our research as inclusive and wide-reaching as possible. This will not be stored with the research data and will not have any identifiable information included in the EDI questionnaire.

Participants will then begin the image acquisition process. The investigator will ensure the equipment is set up ready for use. This includes: the study laptop (with the CapilyticsAcquisition software installed), Dino-Lite CapillaryScope, oil and pipette. The Dino-Lite CapillaryScope is a portable, handheld microscope that will be connected to the laptop provided to each participating site. Pre-session checks will be required prior to image acquisition (e.g., ensuring

the Dino-Lite CapillaryScope is plugged in to the laptop). A small amount of oil will be placed along the nailfold of each finger prior to imaging to improve image quality. The imaging session will then begin. After a short calibration task, the software will guide the user to acquire nailfold capillaroscopy images from eight digits (thumbs excluded). The Dino-Lite CapillaryScope will be cleaned after each participant to minimise the risk of transmission of infection.

After the examination, the participant will be asked to complete a short questionnaire about their experience of the procedure. The clinical team member performing the examination will be asked to complete a short questionnaire about their experience of the procedure after the first and last participant they image. This will include a set of 10 questions for assessing the usability of the system on the standardised System Usability Scale (SUS).

Questionnaires will be made available to complete online using Qualtrics or using paper copies.

Following the examination, a simple report including representative images from the examination will be provided to the rheumatologist. Based on this, and any other clinical information available, the clinician will be asked to provide their opinion of the degree of vessel abnormality present, and their patient management decision. Once this data has been collected, a full clinical report will be released, providing an abnormality score, based on the nailfold capillaroscopy images with reference to a normal range, and a grading on a clinically relevant four-point scale:

1. Normal
2. Probably normal
3. Probably abnormal
4. Definitely abnormal

Other features of the report include:
- An indicator of image quality
- A report of capillary parameters (e.g. width and density)
- Raw image data
- Supporting data

The report is intended to be for research use only and is not intended to be relied upon to make a diagnosis or to guide management of the patient. All clinical decisions should be made prior to receipt of the report.

At the end of the study, all images collected and reports generated will be reviewed by a panel of capillaroscopy experts to establish a definitive categorisation of the degree of vessel abnormality and appropriateness of the report. If there is a discrepancy between the diagnosis and the clinical report, the report and capillaroscopy images will be reviewed immediately by the project clinical Chief Investigator and the clinical care team will be informed.

The utility of reports, usability of the system, and alignment with clinical workflows will be investigated via validated questionnaires and semi-structured interviews with rheumatologists, patients and users.

Patient participants, clinical users including SSc experts with experience of using the Capilytics system will be invited to take part in interviews and focus groups, to gather feedback on the usability, acceptability and impact of the system.

Interviews and/or focus groups with the users of the device will happen in two stages; to explore the onboarding process and towards the end of recruitment to explore overall experiences of using the software. The onboarding interviews/focus groups will take place after at least two and no more than five participants. Users will be asked about their initial experiences of using the software, ease of use, for example "How easy or difficult was it to start using the software?", how helpful the training and inbuilt guidance was, how confident users were using the software with participants, and any suggestions they may have for improving the onboarding experience.

Towards the end of the recruitment period and once users have had regular experience of using the software, they will be invited to take part in a second interview or focus group. This discussion will focus on the overall experience of using the software (from the image acquisition through to the utility of the clinical report). User's will be asked to reflect on how easy it was to use the software in a clinical setting, any challenges faced whilst using the software, how useful the clinical report was when making patient decisions, and suggestions for future improvement.

Interviews and focus groups will be held face-to-face where possible, or remotely (via Microsoft Teams or Zoom), or by phone, depending upon the availability of the participants. Written informed consent will be sought from all participants prior to the focus groups or interviews, including consent to be audio recorded. To maintain anonymity all participants will be assigned a study number.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CapilyticsAcquisition

Primary outcome(s)
1. Image acquisition success: Proportion of investigations completed successfully measured using a review of image quality and report generation using Capilytics software at the single study visit at baseline

2. System usability: Usability score measured using the System Usability Scale (SUS) questionnaire immediately after image acquisition at the single study visit

3. Diagnostic performance – sensitivity: Sensitivity for detecting disease-related vessel abnormalities measured using automated analysis compared with expert diagnosis after image acquisition and report generation at a single visit

4. Diagnostic performance – specificity: Specificity for detecting disease-related vessel abnormalities measured using automated analysis compared with expert diagnosis after image acquisition and report generation at a single visit

The primary endpoints of this project are:
- Proportion of attempted investigations completed successfully, acquiring diagnostic quality images and generating a valid clinical report (feasibility);
- System Usability Score averaged over all users (feasibility);
- Sensitivity of the device in detecting disease-related vessel abnormalities (efficacy);

- Specificity of the device in detecting disease-related vessel abnormalities (efficacy);
- To demonstrate that the CapilyticsAcquisition device is safe and performs as expected under normal conditions of use.

Key secondary outcome(s)
1. Procedure duration: Average per-patient duration of investigation measured using the time recorded during the study visit at the single study visit

2. Patient acceptability: Acceptability of the procedure measured using post-procedure questionnaire at immediately after image acquisition

3. Qualitative usability feedback: Usability and workflow integration measured using semi-structured interviews and focus groups at after completion of image acquisition (subset of participants)

Secondary endpoints of this project are:
- Average per-patient duration of the investigation;
- Qualitative data from users on the strengths and weaknesses of the system;
- Qualitative data from patients on the acceptability of the investigation;
- Analysis of the performance of individual software system components.

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Patient participants:
1. 15 participants per site with established SSc (SSc)-spectrum disorders
2. Adults over 18 years
3. All should fulfil the 2013 ACR/EULAR classification criteria for SSc

Children over 6 years and under 18 years of age (at Alder Hey only):
1. All should fulfil the 2013 ACR/EULAR classification criteria for SSc, OR have juvenile dermatomyositis (JDM)
2. Patients with overlap syndromes may be included, as long as they fulfil the criteria for either SSc or JDM.

1. 30 participants per site presenting with Raynaud’s phenomenon but no previous diagnosis of SSc.
2. Adults over 18 years
3. Patients who are referred for capillaroscopy with Raynaud’s phenomenon, and either a new referral or first seen (at the participating hospital) within the last 2 years

Children over 6 years and under 18 years of age (at Alder Hey only):
Referred primarily with Raynaud’s phenomenon and either a new referral or first seen (at Alder Hey) within the last 2 years

Healthcare Professional participants (qualitative research aspect only):
1. Rheumatologists, vascular technicians, specialist nurses, or similar rheumatology-trained professionals
2. Experience with the use of the Capilytics system during this study.

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
6 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. 15 participants per site with established SSc (SSc)-spectrum disorders:
2. Any reason why nailfold capillaroscopy would be difficult, such as marked finger contractures or painful digital ulcers
3. Diabetes
4. Any disorder limiting the ability to provide informed consent or comply with the study requirements

30 participants per site presenting with Raynaud’s phenomenon but no previous diagnosis of SSc:

1. A defined connective tissue disease (including JDM), vasculitis or inflammatory arthritis (note patients with Very Early Diagnosis of SSc [VEDOSS] may be included, but not patients who fulfil the 2013 classification criteria for SSc or who score 7 or more points on the classification criteria without nailfold capillaroscopy, i.e. if nailfold capillaroscopy is abnormal, they would fulfil the criteria)
2. Presence of a known secondary cause for Raynaud’s phenomenon
3. Any reason why nailfold capillaroscopy would be difficult, e.g. finger deformities
4. Diabetes

Date of first enrolment
22/12/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
England
M6 8HD

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

Study participating centre
Stepping Hill Hospital
Stockport NHS Foundation Trust
Stepping Hill Hospital
Poplar Grove
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Study participating centre
Royal Free London NHS Foundation Trust
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Pond Street
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Study participating centre
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LE1 5WW

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
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AB15 6RE

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available