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Comparing a new low-cost skin examination device with standard equipment used in dermatology clinics

Submission date
18/06/2026

Recruitment status
Recruiting

Registration date
19/06/2026

Overall study status
Ongoing

Last Edited
19/06/2026

Condition category
Skin and Connective Tissue 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
Dermatoscopes are handheld devices used by dermatology clinicians to examine skin lesions in greater detail. Standard dermatoscopes can be expensive, which may limit access in some healthcare settings. The Arclight Dermatoscope attachment is a low-cost device designed to provide dermoscopic examination of skin lesions. This study aims to evaluate how well the Arclight Dermatoscope performs compared with standard dermatoscopes currently used in NHS dermatology clinics and to assess its usability in clinical practice.

Who can participate?
Adults aged 18 years or over attending NHS Fife dermatology clinics with a skin lesion requiring assessment may be eligible to participate.

What does the study involve?
Participants who choose to take part will be asked to provide written informed consent before any study procedures are undertaken. During their routine dermatology appointment, the skin lesion will be examined using both the Arclight Dermatoscope attachment and a standard dermatoscope used in clinical practice. The order in which the devices are used will be randomised. Clinicians will record their assessment and confidence in their decision following each examination.

Additional photographs and dermoscopic images of the lesion will also be taken using study equipment. These images will later be reviewed by dermatology clinicians as part of the research study. Participation is expected to add only a short amount of time to the routine clinic appointment.

What are the possible benefits and risks of participating?
Participants are unlikely to receive a direct benefit from taking part. However, the information gained may help improve access to low-cost dermoscopy in the future and support the development of affordable diagnostic tools for skin lesion assessment.

The study is considered low risk. Dermoscopy is a routine, non-invasive examination technique. Participants may experience minor inconvenience from the additional time required for the study procedures and image capture.

Where is the study run from?
The study is being conducted at NHS Fife Dermatology Clinics in collaboration with the University of St Andrews (UK).

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

Who is funding the study?
The study is funded through UK Research and Innovation (UKRI) funding awarded to the University of St Andrews.

Who is the main contact?
Dr Helena Feasey
University of St Andrews
Email: hraf1@st-andrews.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Helena Feasey

ORCID ID
https://orcid.org/0000-0003-3109-6722

Contact details
University of St Andrews, School of Medicine
North Haugh
St Andrews
United Kingdom
KY16 9TF
+44 1334 463599
hraf1@st-andrews.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
368131

Study information

Scientific Title
Clinical evaluation of the Arclight dermatoscope attachment for primary care skin cancer triage: a prospective diagnostic accuracy study comparing gold-standard dermatoscopes and Arclight

dermatoscope assessments in adults referred to NHS Fife dermatology clinics (Arclight CADET study)

Acronym
Arclight CADET

Study objectives
The primary objective of this study is to evaluate whether clinical intervention decisions made using the Arclight Dermatoscope attachment are concordant with those made using standard dermatoscopes currently employed in NHS dermatology practice.

Secondary objectives are to assess agreement between diagnostic assessments based on dermoscopic images obtained using the Arclight Dermatoscope attachment and a comparator dermatoscope (DermLite DL1), to evaluate clinician confidence when using the devices, and to assess the usability and acceptability of the Arclight Dermatoscope attachment in routine dermatology practice.

The study aims to generate evidence on the clinical performance and practical utility of a low-cost dermoscopy device for the assessment of skin lesions in dermatology clinics.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Device feasibility, Diagnostic, Health services research, Screening

Study type(s)

Health condition(s) or problem(s) studied
Assessment of skin lesions in adults attending dermatology clinics for specialist evaluation.

Interventions

Participants attending NHS Fife dermatology clinics with skin lesions requiring assessment will be invited to take part. Following informed consent, participants will undergo dermoscopic examination using both the investigational device (Arclight Dermatoscope attachment) and a standard dermatoscope used in routine clinical practice. The order of device use will be randomised, and clinicians will record whether an intervention is required and their confidence in the decision.

Dermoscopic images will also be captured using the Arclight Dermatoscope attachment and a smartphone imaging system. Comparator images will be captured using a DermLite DL1 dermatoscope and smartphone imaging system. Anonymised and randomised image sets will subsequently be reviewed by dermatology clinicians blinded to the device used to acquire the images.

All participants will undergo the same study procedures. No additional treatment will be administered, and clinical management will continue according to routine dermatology practice.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Arclight Dermatoscope attachment (investigational device); Heine dermatoscope (clinical comparator used in routine NHS dermatology practice); DermLite DL1 dermatoscope (image-capture comparator).

Primary outcome(s)
1. Intervention decision concordance between Arclight and gold-standard dermatoscopes measured using Intervention required versus not required (binary outcome); proportion concordant and absolute percentage difference in intervention decisions at Single assessment at dermatology clinic visit (baseline)

Key secondary outcome(s)
1. Inter-rater agreement for image reviews measured using Kappa statistic at During blinded image review sessions following completion of image acquisition

2. Clinician confidence ratings measured using Confidence rating on a 1–10 scale (≥6 classified as confident) at Immediately after each lesion examination in clinic

3. Usability and acceptability measured using Clinician questionnaire and qualitative feedback at Clinician feedback collected at study close-out

Completion date
02/12/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Referred to NHS Fife dermatology clinics for assessment of suspicious skin lesions through

standard NHS referral pathways
3. Capable of providing written informed consent prior to any study procedures
4. Able and willing to comply with study procedures, including dermoscopic examination and dermoscopic imaging

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Inability to provide informed consent, e.g. due to cognitive impairment or language barriers without suitable interpreter support
2. Children or young people (<18 years), as the present study is designed for adult referral pathways
3. Lesions deemed clinically inappropriate for dermoscopic examination by the attending dermatologist

Date of first enrolment
19/08/2026

Date of final enrolment
18/11/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Fife
Hayfield House
Hayfield Road
Kirkcaldy

Scotland
KY2 5AH

Sponsor information

Organisation
University of St Andrews

ROR
https://ror.org/02wn5qz54

Funder(s)

Funder type

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be stored in a publicly available repository.

An anonymised participant-level dataset, together with the study protocol, Final Study Report and statistical code, will be made available through the University of St Andrews Research Repository within 12 months of study completion and publication of the primary study results.

The shared dataset will contain de-identified participant-level study data only. No directly identifiable personal data will be included. Data will be anonymised prior to sharing in accordance with applicable data protection legislation and University of St Andrews policies.

Data will be available to researchers, healthcare professionals and members of the public for secondary research, verification of study findings and educational purposes. Access will be subject to any repository terms and conditions and any legal or ethical restrictions necessary to protect participant confidentiality.

Participants are informed during the consent process that anonymised study data may be shared and used for future research. Data will remain available through the repository in accordance with University of St Andrews data retention and research data management policies.

IPD sharing plan summary

Stored in publicly available repository