

Accuracy of diagnosing skin cancers with non-invasive optical coherence tomography (OCT) and line-field confocal OCT (LC-OCT) imaging compared to skin biopsy

Submission date 08/06/2026	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/08/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 26/08/2026	Condition category Cancer	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to investigate the clinical accuracy of two CE-marked non-invasive imaging devices: optical coherence tomography (OCT) and line confocal optical coherence tomography (LC-OCT) in the assessment of skin lesions and the extent to which it can be used to reduce the need for a diagnostic biopsy and its associated clinical and resource costs.

Who can participate?

Patients who have skin lesions planned for skin surgery at Dermatology Department, Royal London Hospital, Barts Health NHS Trust

What does the study involve?

Participants will follow their normal clinical and surgical pathway and those with relevant lesions will be scanned in advance of their procedure with OCT and LC-OCT. The histopathological diagnosis following their surgery will be compared to the diagnosis obtained by the imaging modalities. The comparison will allow us to understand the accuracy of the optical coherence tomography in assessing skin lesions and the extent to which this can be used to reduce the diagnostic need for an invasive skin biopsy and reduce time to diagnosis and treatment.

What are the possible benefits and risks of participating?

The benefits of participating include:

1. Faster diagnosis in the future, helping patients get results more quickly, possibly without the need of a skin biopsy
2. Fewer unnecessary biopsies, which means fewer invasive procedures and less discomfort
3. Better planning before surgery, including more accurate mapping of skin cancers, which can help with treatment decisions and reduce anxiety.
4. Shorter surgeries, particularly during procedures like Mohs surgery, making the experience more comfortable.
5. Improved diagnosis of skin cancer types, such as basal cell carcinoma (BCC), so that the most

suitable treatment can be chosen.

6. Better monitoring of how well treatments work, especially for treatments that target the surface of the skin.

7. Improved ability to tell early cancers apart, such as identifying when a skin condition has started to become more serious.

8. Clearer distinction between harmless and harmful lesions, especially when the appearance of a skin lesion makes diagnosis difficult.

What are the possible disadvantages and risks of taking part?

There is no risk to your safety, as this study uses a non-invasive scanner. However, being part of this study may take a little more time during your clinic visit to complete the questionnaire and the scanning.

Where is the study run from?

Barts Health NHS Trust (UK)

When is the study starting and how long is it expected to run for?

May 2026 to May 2028

Who is funding the study?

Barts Charity (UK)

Who is the main contact?

Prof. Catherine Harwood, catherine.harwood1@nhs.net

Contact information

Type(s)

Scientific, Principal investigator

Contact name

Prof Catherine Harwood

ORCID ID

<https://orcid.org/0000-0002-1375-0965>

Contact details

Department of Dermatology

Royal London Hospital

Whitechapel Road

London

United Kingdom

E1 1FR

+44 (0)7764947063

catherine.harwood1@nhs.net

Type(s)

Public

Contact name

Dr Kapil Bhargava

Contact details

Department of Dermatology
Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1FR
+44 (0)7764947063
kb@dermatologist.london

Additional identifiers

Integrated Research Application System (IRAS)
351678

Study information**Scientific Title**

Optical Coherence Tomography in OutPatient dermatology Units (OCTOPUS): a non-randomised pilot cohort study

Acronym

OCTOPUS

Study objectives

This is a pilot study to establish the feasibility of performing a future phase III trial evaluating the non-inferiority of two CE-marked non-invasive imaging devices (optical coherence tomography, OCT; line confocal optical coherence tomography, LC-OCT) versus the gold standard of clinical assessment and skin biopsy with histopathology in the accurate and cost-effective diagnosis of skin lesions suspicious for skin cancer and precancer.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 27/01/2026, HRA and Health and Care Research Wales (HCRW) (Floor Four, North, Welsh Government Offices Cathays Park King Edward VII Avenue, Cardiff, CF10 3NQ, United Kingdom; -; approvals@hra.nhs.uk; HCRW.approvals@wales.nhs.uk), ref: 25/ES/0097

Primary study design

Observational

Study design

Non-randomised pilot feasibility cohort study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Skin lesions suspicious for keratinocyte skin cancer and pre-cancer

Interventions

Scanning skin lesions using both optical coherence tomography (OCT) and line confocal optical coherence tomography (LC-OCT) prior to skin surgery, which is part of their standard care.

Intervention Type

Other

Primary outcome(s)

1. Interpretation of skin lesions based on scans using the OCT machine prior to skin biopsy made by dermatologists compared to the histological diagnosis obtained through skin biopsy at a single timepoint
2. Interpretation of skin lesions based on scans using the LC-OCT machine prior to skin biopsy made by dermatologists compared to the histological diagnosis obtained through skin biopsy at a single timepoint

Key secondary outcome(s)

1. Patient acceptability, tolerability, and preference of using the OCT and LC-OCT are measured on a questionnaire at a single timepoint
2. Health economic evaluation of OCT and LC-OCT with skin biopsy in the diagnosis of skin lesions using a cost-effectiveness analysis model at a single timepoint
3. Accuracy of diagnosing histological subtyping of basal cell carcinoma on the OCT and LC-OCT compared to the histological diagnosis obtained through skin biopsy at a single timepoint

Completion date

18/05/2028

Eligibility

Key inclusion criteria

1. Participants with skin lesions requiring diagnostic biopsy or excision for diagnosis and referred by consultant dermatologists or specialist dermatology doctors. Lesions will include suspected keratinocyte skin cancer or pre-cancerous lesions, other skin cancers and pre-cancers, benign skin tumours, inflammatory skin conditions, infective disease)
2. Eligible participants will be identified from clinic and surgical lists from the dermatology clinics at Royal London Hospital
3. Adults over the age of 18 years
4. No restrictions on gender
5. Understand and willing to provide informed consent
6. No language restrictions – for those unable to speak English as part of the consent process interpreters who would be required for facilitating routine surgical consent will also be used for study consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

105 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Patients who are unwilling or unable to provide informed consent
2. No patients will be excluded based on gender, language, medical history

Date of first enrolment

18/05/2026

Date of final enrolment

18/05/2028

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Barts Health NHS Trust

The Royal London Hospital

80 Newark Street

London

England

E1 2ES

Sponsor information**Organisation**

Barts Health NHS Trust

ROR

<https://ror.org/00b31g692>

Funder(s)

Funder type

Not defined

Funder Name

Barts Charity

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date