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Using a new non-invasive imaging technique to assess oral pre-cancer and mouth cancer

Submission date 09/07/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/09/2026	**Overall study status** Ongoing	
Last Edited 28/09/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Some conditions in the mouth can develop into mouth cancer if they are not detected and managed early. At present, diagnosis mainly relies on clinical examination and biopsy, which can be invasive and uncomfortable. This study aims to investigate whether a new, non-invasive imaging technique called optical coherence tomography (OCT) and optical coherence tomography angiography (OCTA) can provide detailed images of the mouth lining and its blood vessels to support future diagnosis and monitoring of oral pre-cancer and mouth cancer.

Who can participate?
Adults aged 18 years or over who have suspected or confirmed oral pre-cancer (oral potentially malignant disorders) or mouth cancer

What does the study involve?
Participants will attend one study visit during their routine outpatient appointment. After providing informed consent, they will undergo a non-invasive OCT/OCTA scan of the oral lesion and, where appropriate, nearby normal tissue. The scan takes approximately 20–30 minutes, and participants will also be asked to complete a short questionnaire about their experience.

What are the possible benefits and risks of participating?
Participants are unlikely to receive a direct medical benefit from taking part. However, the study may help develop improved, non-invasive methods for assessing oral diseases in the future. The imaging procedure is non-invasive and considered low risk. Some participants may experience minor discomfort from holding the imaging probe inside the mouth during scanning.

Where is the study run from?
University of Dundee Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2026 to September 2027

Who is funding the study?
Tay Health Tech

Who is the main contact?
Dr Chunhui Li, c.li@dundee.ac.uk

Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Study information

Scientific Title
Optical coherence tomography and angiography imaging of oral mucosa in patients with oral potentially malignant disorders and oral cancer

Acronym
OROCTA

Study objectives
The primary objective of this study is to evaluate the feasibility and acceptability of optical coherence tomography (OCT) and optical coherence tomography angiography (OCTA) for imaging oral potentially malignant disorders (OPMDs) and oral squamous cell carcinoma (OSCC). Secondary objectives are to assess image quality and explore structural and vascular imaging biomarkers that may support the future development of non-invasive diagnostic tools for oral cancer.

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
Uncontrolled

Assignment
Single

Purpose
Device feasibility, Diagnostic, Prevention, Screening

Study type(s)

Health condition(s) or problem(s) studied
Oral potentially malignant disorders (OPMDs) or oral squamous cell carcinoma (OSCC)

Interventions
Participants will attend a single study visit during a routine outpatient appointment. Following informed consent, they will undergo non-invasive intraoral optical coherence tomography (OCT) and optical coherence tomography angiography (OCTA) imaging of clinically suspicious oral lesions and, where feasible, adjacent normal mucosa. Up to three scans will be acquired at each imaging site to optimise image quality and assess reproducibility. Participants will also complete a brief acceptability questionnaire after imaging. The imaging procedure will not alter routine clinical management, and no additional treatment will be provided as part of the study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Custom-built swept-source optical coherence tomography (SS-OCT) and optical coherence tomography angiography (OCTA) system

Primary outcome(s)
1. Successful acquisition of analysable OCT/OCTA images measured using the proportion of participants with OCT/OCTA images of sufficient quality for analysis at baseline (single imaging visit)

2. Participant-reported acceptability measured using a post-imaging questionnaire at immediately after the imaging procedure (baseline visit)

3. Image quality measured using the predefined OCT/OCTA image quality grading system at baseline (single imaging visit)

Key secondary outcome(s)

Completion date

30/09/2027

Eligibility

Key inclusion criteria
1. Patients with clinically suspected or histologically confirmed oral potentially malignant disorders (OPMDs) and/or oral squamous cell carcinoma (OSCC)
2. Adults aged 18 years or older
3. Able and willing to provide written informed consent
4. Patients with clinically suspected or histologically confirmed oral potentially malignant disorders (OPMDs) or oral squamous cell carcinoma (OSCC)
5. Able to tolerate intraoral OCT/OCTA imaging during a single study visit

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unable or unwilling to provide written informed consent
2. Unable to tolerate intraoral OCT/OCTA imaging (e.g., severe trismus or inability to maintain the required position)
3. Currently participating in the interventional phase of another clinical trial
4. Any medical condition that, in the opinion of the investigator, would compromise participant safety or study integrity

Date of first enrolment
01/10/2026

Date of final enrolment
01/09/2027

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Dundee
Perth Road
Dundee
Scotland
DD1 4HN

Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type

Funder Name
Tay Health Tech

Alternative Name(s)
Dundee University, Oilthigh Dhùn Dè

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available