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Rapid screening of cheek cells to distinguish cancer using light

Submission date	Recruitment status	[ ] Prospectively registered
09/09/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/10/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/02/2024	Respiratory	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Non-small cell lung cancer (NSCLC) is the UK's leading cause of cancer deaths. Early diagnosis of lung cancer is key to improving survival rates. Most patients aren't diagnosed until stage 4, when a cure is often not possible. Sierra Medical are developing a new and unique non-invasive screening test to detect NSCLC from a simple cheek swab with extremely high accuracy. To get the technology approved for use in hospitals, they need to conduct a series of clinical trials. This is the first clinical trial required to gain approval.

Who can participate?
1. Non-smokers with no history of lung disease
2. Current or ex-smokers with no history of lung disease
3. Current or ex-smokers with confirmed COPD
4. Current or ex-smokers with lung cancer (NSCLC only)
5. Smokers and non-smokers with other types of lung cancer
All aged 18 years and over

What does the study involve?
Participants will be seen in a research clinic where medical history will be obtained, lung function tests are performed and two cheek swabs are taken. These swabs will be analysed to demonstrate that there is a difference between cells from patients with and without lung cancer.

What are the possible benefits and risks of participating?
There will be no immediate benefit to the participant. However, if the study is successful participants will contribute to developing a lung cancer screening test that will enable earlier detection of lung cancer which will provide better outcomes to future lung cancer patients. The participant will be paid £10 to cover time and travel. There are very few risks associated with participation in the study, however, the participant may experience temporary irritation to the inside of their cheek where they were swabbed and/or temporary dizziness from forced exhalation during the lung function test (spirometry). Both side effects are rare and temporary.

Where is the study run from?
Queen Alexander Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2019 to June 2024

Who is funding the study?
1. Innovate UK
2. Sierra Medical Ltd (UK)

Who is the main contact?
Thomas.macdonald@porthosp.nhs.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
257831

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 257831, CPMS 41596

Study information

Scientific Title
Infrared analysis of buccal cell swabs as a novel non-invasive screening test for lung cancer in individuals exposed to carcinogens

Acronym

RADiCAL

Study objectives
Infrared (IR) fingerprints collected using lab-based IR micro-spectroscopy of individual human buccal mucosa cells can be used to differentiate between smokers with non-small cell lung cancer (NSCLC) and smokers/non-smokers without NSCLC with sufficient accuracy to be used as an initial screening test for lung cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2019, South Central - Berkshire Research Ethics Committee (Bristol REC Centre, Whitefriars, Level 3, Block B Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)20 7104 8057; berkshire.rec@hra.nhs.uk), ref: 19/SC/0100

Study design
Observational study

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD) and/or non-small cell lung cancer

Interventions
Patients will attend one study visit where the following will be obtained/performed:
1. Informed consent
2. Specific medical history
3. Brief medical history
4. Smoking history
5. Assessment of food and other potential contaminates
6. Collection of cheek swabs
7. Lung function test (spirometry)
8. Confirm eligibility
9. Record adverse events
10. Acceptability questionnaire

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sierrra AIR-DS

Primary outcome measure
Individual infrared (IR) spectra collected from each participant's cheek cells using a Fourier-transform infrared spectroscopy (FTIR) microspectrometer at a single timepoint

Secondary outcome measures
Average IR spectra of buccal mucosa swabs measured using a benchtop ATR-FTIR spectrometer for smokers with NSCLC and smokers/non-smokers without NSCLC at a single timepoint

Overall study start date
20/03/2019

Completion date
30/06/2024

Eligibility

Key inclusion criteria
There are five arms of the study. Approximately 100 participants will be recruited into the following four groups:
A. Non-smokers with no history of lung disease
B. Current or ex-smokers with no history of lung disease
C. Current or ex-smokers with confirmed COPD
D. Current or ex-smokers with lung cancer

An additional exploratory group of up to 50 participants will be recruited:
E. Smokers and non-smokers with heterogenous lung cancers or suspected lung cancer

1. Are able to understand and provide signed consent – All groups
2. Are aged 18 years or older – All groups
3. Are able to provide a cheek swab sample – All groups
4. Are a non-smoker and never used e-cigarettes – Group A only
5. Are a smoker or ex-smoker – Group B, C and D
6. Must have spirometry of FEV1/FVC ratio >0.7 - Group A and B
7. Are diagnosed with COPD and meet the GOLD criteria for COPD (post-bronchodilator airway obstruction with FEV1/FVC ratio <0.7) Group C only
8. Have (or eventually proven to have) a histologically-confirmed primary non-small cell lung cancer - Group D only
9. Have not commenced treatment for non-small cell lung carcinoma - Group D only
10. Have (or eventually have) a histologically-confirmed cancer a) other than a NSCLC (e.g. small-cell cancer, carcinoid) or b) NSCLC but have never smoked or c) NSCLC but have received treatment – Group E only

Participant type(s)

Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
700

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/05/2019

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Sierra Medical

Sponsor details
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Sponsor type
Industry

Website
https://www.sierramedical.co.uk

Funder(s)

Funder type
Industry

Funder Name
Sierra Medical

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The final clinical study report will be produced after study completion. It is intended that the results from this research will be submitted to a high-impact peer-reviewed journal, once the study is complete.

Intention to publish date
05/05/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to commercial sensitivity

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No