Rapid screening of cheek cells to distinguish cancer using light

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

Contact name

Prof Anoop Chauhan

Contact details

Portsmouth Hospitals NHS Trust Queen Alexandra Hospital Southwick Hill Road Cosham United Kingdom PO6 3LY +44 (0)2392286000 anoop.chauhan@porthosp.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

257831

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 United Kingdom

England

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

Sponsor information

Organisation

Sierra Medical

Funder(s)

Funder type

Industry

Funder Name

Sierra Medical

Funder Name

Innovate UK

Alternative Name(s)

UK Research and Innovation Innovate UK, innovateuk

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 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes