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FINE: Imaging fibrosis in lung cancer and relating findings to outcomes of treatment

Submission date
17/11/2021

Recruitment status
No longer recruiting

Registration date
15/02/2022

Overall study status
Completed

Last Edited
06/12/2023

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Lung cancer is the leading cause of cancer related death worldwide and most patients have progressive disease or relapse despite therapy and new therapies that target the immune system. The tumour microenvironment (TME) is a collection of several different cell types, including a cell called fibroblasts. The fibroblasts within lung cancer express a protein called FAP and this protein can now be imaged using scans called PET scans. Therefore, using imaging (with a specialised PET scan) could allow us to determine which patients have a FAP active tumour, and which do not, which in turn could inform us as to which patients may need additional treatments targeting the TME/fibroblasts to help therapy be more effective. This study looks to lay the foundations for the use of PET imaging of FAP in NSCLC by using small numbers of patients who have been diagnosed with lung cancer and perform a FAP-PET scan at a single time point, following which the patients all receive their usual standard care. We will recruit patients who are planned to have surgical excision of the tumour, as well as patients who are due to have drug based anti-cancer therapy (including immune targeting regimes). This study looks to help us understand if the FAP-PET signal corresponds to i) the amount of FAP active fibroblasts in a tumour and ii) if this can potentially indicate subsequent failure of treatment, prior to subsequent larger trials.

Who can participate?
Participants aged over 50 years old with confirmed lung cancer who are either undergoing planned surgical resection (cohort 1) or planned systemic oncological treatment (cohort 2)

What does the study involve?
The study involves eligible participants undergoing a research PET scan. They may also be asked to provide a small blood sample, up to 20mls. If the participant is on the surgical pathway (cohort 1), we will also obtain a sample of lung tissue following surgery. Participants clinical records will be followed-up for up to 1 year

What are the potential benefits and risks of participating?
The PET scan is an extra scan in addition to routine care, therefore there is small increase in the amount of radiation exposure.
There is a potential risk of an allergic reaction to the radiotracer which is very rare (serious

allergic reactions occur in approximately 1 in 10,000 patients) and we have clear procedures for managing such reactions. There is also a small risk of bleeding, bruising and infection from the cannula insertion but we will follow a sterile procedure.

Where is the study run from?
Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
April 2021 to December 2023

Who is funding the study?
Cancer Research UK

Who is the main contact?
Dr Ahsan Akram, ahsan.akram@ed.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Ahsan Akram

ORCID ID
https://orcid.org/0000-0003-4605-1682

Contact details
University of Edinburgh
Centre For Inflammation Research
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
United Kingdom
EH16 4TJ
+44 (0)131 2429180
ahsan.akram@ed.ac.uk

Type(s)
Public

Contact name
Mrs Katie Hamilton

Contact details
University of Edinburgh
Centre For Inflammation Research
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
United Kingdom

EH16 4TJ
+44 (0)131 2429180
k.hamilton@ed.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
299962

Central Portfolio Management System (CPMS)
51140

Protocol serial number
AC21071

Study information

Scientific Title
Imaging Fibroblast Activation Protein (FAP) in non-small cell lung cancer using PET scan and correlation with outcomes of usual therapy.

Acronym
FINE

Study objectives
Can fibrosis activity (measured by FAP specific PET-CT) be correlated with the response to therapy in non-small cell lung cancer?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/08/2021, West of Scotland REC 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, PAISLEY, PA2 7DE, UK; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 21/WS/0094

Primary study design
Observational

Study design
Single-site observational cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Lung cancer

Interventions

Eligible participants from both cohorts, will undergo a research scan (PET-CT scan using the FAP radiotracer) and it is possible the eligibility assessment/consent occur on the same day as the scan. Blood will be drawn at consent and at the time of the PET-CT scan if on separate days.

Cohort 1 will undergo resection of their tumour and once the specimen has been resected areas of tumour and non-cancerous lung will be dissected by a trained pathologist of ex-vivo assays undertaken in the University of Edinburgh. The surgical resection forms part of the routine care. The additional specimens taken by the research team form part of the study. No further study interventions will be undertaken with cohort 1, though in an observational manner the cohort will have their notes reviewed for up to 1 year for outcome metrics.

Cohort 2 will include patients who are referred to medical oncology for systemic anti-cancer therapy. Following the PET-CT, no further study interventions will be undertaken with cohort 2, though in an observational manner the cohort will have their notes reviewed for up to 1 year for outcome metrics, including routine care CT scans that may be undertaken.

Intervention Type
Other

Primary outcome(s)
Cohort 1 (measured at the time of resection):
1. The degree of fibrosis on the 68Ga-FAPI scan measured by SUV (standardised uptake volume) over a ROI (region of interest)
2. Markers of fibroblast activation from the excised tissue (measured by multiparametric flow cytometry analysis), including FAP, CD34, aSMA, podoplanin)

Cohort 2:
1. The degree of fibrosis on the 68Ga-FAPI scan measured by SUV (standardised uptake volume) over a ROI (region of interest) measured at the time of resection
2. Treatment response measured by visual inspection of CT scan using RECIST and iRECIST methods post treatment and on usual scans up to 1 year

Key secondary outcome(s)
Cohort 1: Laboratory markers including T-cell phenotypes within the tumour measured using biopsy at the time of resection
Cohort 2: Progression free survival and mortality measured using patient records up to 1 year

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Capacity to provide informed consent
2. Confirmed lung cancer for which surgical resection is being planned (Cohort 1)
3. Confirmed lung cancer (cohort 2) planned for systemic oncological treatment
4. Treatment naïve patients ≥50 years
5. Thoracic CT scan taken within the previous 12 weeks
6. ECOG performance status 0-2

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 Years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Inability or unwilling to give informed consent.
2. Unable to tolerate the supine position
3. Impaired renal function with eGFR of <30 mL/min/1.73m²
4. Severe or significant comorbidity that prevents systemic oncological therapy or performance status 3 or 4
5. Women who are pregnant or breastfeeding

Date of first enrolment
19/11/2021

Date of final enrolment
10/10/2022

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Old Dalkeith Road
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Organisation
NHS Lothian

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and during the current study will be available upon request from the study team following completion of the study. (ahsan.akram@ed.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2	24/08/2021	17/11/2021	No	Yes