A clinical imaging Study of the changes in [18F]F-AraG uptake following radiotherapy in Non-small cell lung cancer.

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This study has been transitioned to CTIS with ID 2024-517960-45-00 check the CTIS register for the current data. • To assess the relative change in uptake of [18F]F-AraG in tumor lesions upon anti-PD-1 treatment• To assess the relationships between...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON52284

Source
ToetsingOnline

Brief title
SHARP

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
breast cancer, esophageal cancer, lung cancer, lung carcinoma, melanoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Boehringer Ingelheim

Intervention

Keyword: [18F]F-AraG, NSCLC, PET imaging, radiotherapy

Outcome measures

Primary outcome

1.To assess the relative change in uptake of [18F]F-AraG in tumor lesions on

anti-PD-1 treatment

a. To define tracer uptake in all tumor lesions and lymphoid organs (lymph

nodes, spleen) per [18F]F-AraG PET scan

b. To assess the changes in uptake between baseline and after 1 and 3 weeks

on-treatment

Secondary outcome

N/A

Study description

Background summary

The efficacy of immunotherapy and patient selection for combinatorial immunotherapy strategies would greatly improve if the tumor microenvironment (TME) could be characterized more accurately. Positron emission tomography (PET) using tracers that target immune cell subsets may provide a non-invasive means to immune-profile the TME. Imaging T-cells will greatly help in identifying *hot* tumors, or parts of the tumor mass that have high concentrations of tumor infiltrating T-cells. A promising tracer to image activated T-cells is [18F]F-AraG. We hypothesized that baseline tumor [18F]F-AraG uptake and increase of tumor [18F]F-AraG accumulation will give a good indication of in-vivo changes in the TME upon radiotherapy. As [18F]F-AraG will accumulate in activated T-cells, and the concentration of activated

T-cells will increase in the TME onradiotherapy, we expect that tumor [18F]F-AraG uptake will increase on radiotherapy. Therefore, the aim of this project is to investigate the changes in tumor uptake of [18F]F-AraG in cancer patients

Study objective

This study has been transitioned to CTIS with ID 2024-517960-45-00 check the CTIS register for the current data.

• To assess the relative change in uptake of [18F]F-AraG in tumor lesions upon anti-PD-1 treatment
• To assess the relationships between baseline tumor [18F]F-AraG uptake, change of tumor [18F]F-AraG uptake and tumor response to anti-PD-1 therapy

Study design

single center, single arm, open-label, non-controlled, non-randomised imaging trial, N=12

Intervention

all patients will undergo 3 [18F]F-AraG PET scanning procedures according to the institutional protocols

Study burden and risks

All patients will undergo 3 [18F]F-AraG scanning procedures. Prior to the injection of tracer, venous blood will be drawn for immunological assessment of PBMC*s. Per scanning procedure, patients will be lying for approximately 90 minutes on the scanner and patients will receive a radiation burden of 5.7 mSv per scanning procedure. In all patients, a venous cannula will be inserted in an arm vein and to drawn blood (7cc), manually at 2 time point. Patients will derive no direct benefit from participating in this trial. The insights obtained in the translational part of this study can be of high interest for future cohorts of cancer patients.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV

NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Histologically confirmed NSCLC, melanoma, esophageal, or breast cancer
• Ongoing immunotherapy using an anti-PD-(L)1 agent
• Planned to be treated with high dose (24Gy) radiotherapy per clinical indication
• Be willing and able to provide written informed consent for the trial.
• Have a performance status of 0-2 on the ECOG Performance Scale
• Be above 18 years of age on day of signing informed consent.

Exclusion criteria

• Subjects with a condition requiring systemic treatment with either corticosteroids (>10 mg daily prednisone equivalent) or other immunosuppressive medications within 14 days of day 0. Inhaled or topical steroids, and adrenal replacement steroid >10 mg daily prednisone equivalent, are permitted in the absence of active autoimmune disease.
• Psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the trial.
• Patient is pregnant or breastfeeding, or expecting to conceive within the projected duration of the trial, starting with the screening visit through 12

weeks after the last administration of [18F]F-AraG.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-11-2022
Enrollment:	12
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	[18F]F-AraG
Generic name:	[18F]F-AraG

Ethics review

Approved WMO Date:	20-04-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-08-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2024-517960-45-00
EudraCT	EUCTR2021-003986-36-NL
CCMO	NL78588.029.21