

Follow up after curative-intent lung cancer treatment

Submission date 07/02/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/02/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 15/03/2023	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Lung cancer is a common disease. Unfortunately, the majority of lung cancers are diagnosed too late to receive treatment. When an earlier diagnosis is made it is easier to treat the cancer, usually by removing the tumour from the lung. However, recurrence of lung cancer is quite frequent, particularly during the first two years after treatment. This is why most experts recommend regularly scheduled imaging procedures (scans that take pictures of organs inside the body) after treatment of lung cancer as a form of surveillance. Usually, computed tomography (CT) of the chest is recommended. A CT scan uses X-rays (radio waves) controlled by computers to create three dimensional images. With increases in technology, there are new types of CT scans such as PET-CT scan. A PET-CT scan combines nuclear imaging (using a radioactive drug to create a picture) with a CT scan. It has been shown that PET-CT can detect some lung cancer better than a CT does. So far, in surveillance after lung cancer treatment, the performances of these two methods have never been compared. The aim of this study is to compare the CT scan and the PET-CT scan to see how well they are able to detect lung cancer.

Who can participate?

Adults who have completed a treatment for lung cancer.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive a CT scan every six months for two years. This involves being injected with a special dye and then laying flat in a bed underneath the scanner for a couple of minutes. Those in the second group receive a PET-CT scan every six months for two years. This involves being injected with a special radiotracer (dye) and then laying flat in a bed in the centre of the large, circular scanner for about an hour. After the scans, the images are discussed by a board of experts. The treating physician explains the results of the images to the patient. Participants receive regular follow up after the study if they do not show any scans of anything suspicious. Participants who show scans of suspicious or unexplained findings are given further diagnostic steps and treatment.

What are the possible benefits and risks of participating?

Participants may benefit from receiving multiple scans in order to screen for recurring lung cancer. There are potential risks involved with imaging procedures such as allergies to the contrast medium (dye) and exposure to radiation.

Where is the study run from?

Cantonal Hospital Aarau (Switzerland)

When is the study starting and how long is it expected to run for?

October 2011 to August 2014

Who is funding the study?

Research Council of the Cantonal Hospital Aarau (Switzerland)

Who is the main contact?

Dr Sarosh Irani

Contact information

Type(s)

Public

Contact name

Dr Sarosh Irani

Contact details

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Additional identifiers

Protocol serial number

Protocol No 2011/045

Study information

Scientific Title

Surveillance of lung cancer patients with integrated PET-CT or contrast-enhanced CT after curative-intent treatment: a prospective, randomized study

Study objectives

The aim of this current prospective randomized study is to compare contrast-enhanced chest CT scan and integrated PET-CT scan in cancer surveillance after curative-intent treatment of NSCLC patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee of the Cantonal Aarau Switzerland, 27/09/2011, ref: 2011/045

Primary study design

Interventional

Study design

Prospective single centre randomized study

Study type(s)

Screening

Health condition(s) or problem(s) studied

Non-small cell lung cancer

Interventions

Participants who have completed a curative-intent treatment are randomly allocated to one of two groups.

Group 1 (Contrast-CT): Participants receive a CT scan every six months for two years. This involves being given a contrast medium through the use of an intravenous catheter (usually placed into a vein of one arm) and images are taken within thirty seconds. Computed tomography multidetector (MDCT) examinations of the chest are performed using either a 64 or a 320 detector-row CT scanner (Aquilion 64 CT / Aquilion ONE CT; Toshiba Medical Systems, Otawara, Japan). All chest MDCT examinations are obtained with the routine low dose chest MDCT protocol including craniocaudal direction, supine position with both arms raised above the head, single breath hold and a scan volume ranged from the level of the diaphragm to a level just above the thoracic inlet. The injected volume of contrast medium (Iopromide 300, Ultravist 300; Bayer Vital GmbH, Leverkusen, Germany) is tailored to the individual body weight: <50 kg = 60ml @ 2ml/second vs. ≥ 50kg = 80ml @ 2.5ml / second with a fixed contrast delay of 35 seconds. Radiation dose exposure is systematically reduced by various methods including automatic exposure control (Toshiba Sure Exposure 3D) and iterative reconstruction algorithms (Toshiba Adaptive Iterative Dose Reduction ADIR 3D).

Group 2 (Integrated PET-CT): Patients receive an integrated PET-CT scan every six months for two years. This involves being given radiolabeled glucose (18F-FDG, a dose regimen of 5 MBq/kg body weight) through an intravenous catheter (usually placed into a vein of one arm). The PET scans start 60 minutes after tracer injection, scanning from the vertex of the skull to the middle of the thigh. A Siemens Biograph MCT 40 PET scanner is used with high resolution reconstruction software (HD PET), also incorporating the time-of-flight information in the reconstruction algorithm (TOF PET). Low dose CT scans are performed for attenuation correction of the PET images. The PET scanner is fully cross-calibrated, allowing accurate SUV measurements. Scans are performed according to the manufacturer's recommendations and based on the regulations of the Swiss health authorities.

A few days after the scan the participants from both groups attend an outpatient department clinical visit to discuss the results of the investigation with the treating physicians. The recommendations of the interdisciplinary board for further diagnostic or therapeutic steps are communicated to the patient during this visit. If the images are not suspicious the next scan is

scheduled after six months. If there are suspicious or unexplained findings further diagnostic steps (usually biopsy) are undertaken.

Intervention Type

Device

Primary outcome(s)

Cancer recurrence or second primary cancer is assessed by further work up of a pathological finding in contrast-CT or PET-CT (the particular method of diagnostic work up is board-defined and does usually consist of either endoscopic or surgical biopsy) respectively and is performed at 6, 12, 18 and 24 months.

Key secondary outcome(s)

1. Other pathological finding are measured through surveillance CT or PET-CT scans at 6, 12, 18, and 24 months
2. Symptomatic recurrences/patient pursuing medical help due to somatic symptoms is measured by methods that are chosen by the treating physician at any time when symptoms occur. Usually, these methods consist of computed tomography or magnet resonance imaging. The decision about the methods chosen in these situations is not part of the current study.

Completion date

29/08/2014

Eligibility

Key inclusion criteria

1. 18 years of age or older
2. Have a FDG-PET positive tumor
3. Completed a curative-intent treatment for NSCLC (the PET positivity and the curative character of the cancer therapy are board defined)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Sex

All

Total final enrolment

96

Key exclusion criteria

1. Lack of written informed consent
2. Insufficient knowledge of the German language
3. Impaired kidney function (glomerular filtration rate lower than 30 ml/min).

Date of first enrolment

15/01/2011

Date of final enrolment

29/08/2016

Locations

Countries of recruitment

Switzerland

Study participating centre

Cantonal Hospital Aarau

Tellstrasse

Aarau

Switzerland

5001

Sponsor information

Organisation

Clinic of Pulmonary and Sleep Medicine

ROR

<https://ror.org/056tb3809>

Funder(s)

Funder type

Research council

Funder Name

Research Council of the Cantonal Hospital Aarau, Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due to confidentially reasons.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	31/07/2019	Yes	No
Results article		04/12/2019	15/03/2023	Yes	No
Participant information sheet	version V2	15/02/2017	14/03/2017	No	Yes