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Follow up after curative-intent lung cancer treatment

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

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 in 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 a 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Prospective single centre randomized study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See additional files (in German)

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 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 invovles 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 scull 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 measure
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.

Secondary outcome measures
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.

Overall study start date
11/10/2011

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

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
40 patients in each group would be necessary.

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

Sponsor details

Cantonal Hospital Aarau
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/056tb3809

Funder(s)

Funder type
Research council

Funder Name
Research Council of the Cantonal Hospital Aarau, Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed medical journal.

Intention to publish date
31/12/2017

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?
Participant information sheet	version V2	15/02/2017	14/03/2017	No	Yes
Results article	results	01/02/2019	31/07/2019	Yes	No
Results article		04/12/2019	15/03/2023	Yes	No