'A one-day diagnostic track for lung cancer suspects from chest X-ray using PET-CT and subsequent multiple endoscopic investigations. (including bronchoscopy, EUS-FNA and EBUS-TBNA)'.

Published: 29-08-2006
Last updated: 20-05-2024

1. to study feasibility of a fast one-day diagnostic track including PET-CT and subsequent diagnostic/ staging investigation depending on PET-CT findings. to determine:2. the percentage of patients in which the one-day track is sufficient for...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract neoplasms
Study type	Interventional

Summary

ID

NL-OMON29952

Source
ToetsingOnline

Brief title
Fast-track diagnosis for lung cancer suspects with PET-CT and EUS-EBUS.

Condition

- Respiratory tract neoplasms

Synonym
fast diagnosis of lung cancer suspects., one-day diagnostic tracking for lung cancer suspects

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: maatschap longziekten.

Intervention

Keyword: endoscopic techniques, fast-track diagnosis, lung cancer, PET-CT

Outcome measures

Primary outcome

1. Number of patients that will have a definitive diagnosis and final

stage NSCLC in one day.

2. Time between chest X-ray with suspicion on lung cancer

and the first visit to the outpatient clinic.

3. Time between the first outpatient clinical contact and informing patient

about definite diagnosis.

4. Time from the definite diagnosis until the initiation of therapy.

Secondary outcome

1. Number of patients able to have all diagnostic tests in one-day.

2. Number of tests and procedures that have been performed.

3. Patient satisfaction with the one-day procedure.

4. Sensitivity of EUS-FNA and EBUS-TBNA when immunohistochemical

analysis is added to investigate false negative procedures.

Study description

Background summary

Patients have to pass different diagnostic phases in their analysis of a chest X-ray suspicious for lung cancer. Long waiting times with uncertainty about the outcome are a waste of time and unacceptable for the patient. Hospital visits as a consequence of this are a financial burden. Important reasons for physicians to shorten diagnostic tumor analysis. Shortening and intensifying the diagnostic track by combining diagnostic and staging procedures would preclude unnecessary tests and procedures, lowering the total hospital costs per patient and may lead to more satisfaction for patient and physician.

PET-CT is the most important imaging tool for lung cancer analysis and better than CT or FDG-PET alone, but not optimal for determination of tumour invasion in mediastinal or other adjacent structures. MRI is more suitable for this purpose, but is limited available. EUS-FNA (carinal lymph nodes), eventually in combination with CT or FDG-PET and EBUS-TBNA (right mediastinal lymph nodes), superior to TBNA alone, are novel imaging techniques with a high accuracy. Bronchoscopy provides information on tumour type and resectability of centrally but not peripherally located tumours. Mediastinal staging can be performed by adding TBNA to bronchoscopy with high accuracy. PET-CT, as a superior imaging mode, could direct for the best subsequent endoscopic technique for obtaining a tissue diagnosis as well as leading to a more comprehensive staging of patients with suspected lung cancer.

False negative findings could be caused by sampling errors or false interpretations by the cytopathologist of specimens with tumour cell poverty. A more sensitive immune histochemical analysis could modify EUS-FNA and EBUS-TBNA results.

Study objective

1. to study feasibility of a fast one-day diagnostic track including PET-CT and
subsequent diagnostic/ staging investigation depending on PET-CT findings.

to determine:

2. the percentage of patients in which the one-day track is sufficient for diagnosis
and staging needing no more further investigations.
3. the time-spans needed for diagnosis (including staging and function tests) of
the patients in comparison to a historical study group.
4. the amount of investigations needed to obtain the diagnosis compared with a historical study group.
5. the effect of immuno-histochemical analysis on the sensitivity of data of diagnostic procedures.

Study design

A Prospective, open, single center, study.

Patients who are admitted to the outpatient pulmonology department by a general practitioner or specialist with a chest X-ray suspicious for lung cancer with an age between 18 and 80 years are suitable for participation. The X-ray and referral are studied by a chest physician (by phone or fax). Selected patients are invited to enter the study after answering a questionnaire by phone (p. 31).
The questionnaire screens patients* interest, co-morbidity and medication use. Informed consent forms, patient information forms and a time table for the diagnostic day are provided by mail or E-mail in cases where time gets short. Waiting time to enter the study will be no longer than one week.

Hundred patients will be recruited by means of informed consent. In a narrow logistic scheme the study subjects will undergo a diagnostic work up to a maximum of 3 patients per study day (p. 32). Patients will be admitted at the pulmonary ward for the study day and will be accompanied by nurses. All patients will get PET-CT scanning in the morning of the study day. Depending on the location of lesions seen on PET-CT, further invasive diagnostic procedures will be planned for the afternoon, according to a scheme outlined on page 33. In the meanwhile, routine blood tests, EKG and pulmonary function tests are done. The invasive diagnostic procedure to be chosen, has to provide ideally a diagnosis and stage at one time.

Mediastinal and adjacent structures will be analysed with EUS-FNA or EBUS-TBNA. EBUS-TBNA will be used for right mediastinal lymph nodes. Carinal lymph nodes are biopsied with EUS-FNA. Mediastinal staging will be done with bronchoscopy alone for central located tumors, peripherally located lesions will be analysed with EUS-FNA or bronchoscopy in combination with EBUS-TBNA.

When enough material is available, cytologic specimen will be stored in cell casts fixed in agar. In case of negative biopsies, surgical verification follows. When this verification proves that cytologic biopsies were false negative, immune histochemical analysis on the agar imbedded material will be done retrospectively.

When patients are recovered from their diagnostic procedure, they will leave the hospital with an appointment for a visit one week later to be informed about their diagnosis and treatment. Additive appointments will be made on a term as short as possible and necessary when extra diagnostic tests are needed like MRI, exercise tests, perfusion tests or evaluation by other consultants.

The percentage of patients in which this diagnostic track leads to a diagnosis and tumor stage in one day will be determined. The number of tests and

diagnostic procedures needed to obtain a diagnosis, including tumor stage (especially final stage NSCLC) and function tests, will be compared with a historical matched study group. This historical study group is chosen from an era before the availability of integrated PET-CT and ultrasound guided endoscopic tools and meets the same inclusion and exclusion criteria as the patients in this study. The timelines from initial chest X-ray to diagnostic day to informing the patient to start of treatment will be determined. These figures will be compared with the historical study group.

Finally, patients will be asked to fill in a patient satisfaction questionnaire concerning the one-day diagnostic program track, the informative visit and after an eventual successive treatment start (p. 31).

Intervention

One-day diagnostic track using PET-CT eventually with bronchoscopy, EUS-FNA , EBUS-TBNA and ultrasound guided transcutaneous biopsies.

Study burden and risks

There are no different adverse effects due to the diagnostic program. Patients in
the one-day diagnostic track will undergo the same diagnostic interventions as patients outside the study. The risk of bleeding and infection due to the EUS and EBUS procedures must be mentioned, although patients would be undergo these biopsies even if they would not participate to this trial; there is no *additive risk*.
The burden is that the whole diagnostic program could lead to psychological distress because of the several investigations within a relatively short period. Patients with claustrophobia might be anxious during the PET-CT. The expected benefits are a patient satisfaction due to short diagnostic timeframes, lesser diagnostic procedures and faster decision making in therapeutic options.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

patients with suspicion of lung cancer on chest X-ray.
age between 18-85.
informed consent.

Exclusion criteria

comorbidity (alcoholabuse, drugsabuse, limiting psychiatric illness)
non-compliance
previous diagnostic tests for the suspicious chest X-ray (endoscopy, CT)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2006
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	29-08-2006
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
CCMO	NL12541.075.06