Iodine seed (I-125) as a marker in lung-lesions

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35843

Source
ToetsingOnline

Brief title
Iodine seed (I-125) as a marker in lung-lesions

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Unidentified lung-lesion

Health condition

intrathoracaal (en intraparenchymaal) gelegen longafwijkingen (benigne en maligne)

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: door onderzoekspotje van het ziekenhuis

Intervention

Keyword: I-125, Lung, Marker, Radio-active seed

Outcome measures

Primary outcome

Peroperative localisation

Secondary outcome

Implant procedure

Pathological analysis

Study description

Background summary

In some lung lesions it may be necessary to obtain a histological biopsy. When transthoracal punction and EUS (endoscopic ultrasound)/EBUS (endobronchial ultrasound) fail to obtain a diagnose a surgical biopsy is the next step. Often a VATS (video assisted thoracoscopic surgery) is used for biopsy. When the lung lesion is localized intraparenchymale and thus not visible during VATS, there is a need to localize the lesion. Mostly the localisation is performed using a guide-wire. Short before surgery this guide-wire is placed by the pulmonologist and/or radiologist. This procedure has some disadvantages of which the most important one is dislocation of the guide-wire due to desoufflation of the lung. In some cases there is a need to convert to thoracotomy to localize the lesion. Even then, localisation can be difficult. Other problems which can occur are punction pneumothorax and logistic problems.

Study objective

An alternative for guide-wire localisation might be the use of radio-active seed (I-125) implantation. This marker can easily be identified by means of a gamma-probe. This radio-active seeds are cilindric capsules (approximately 4 mm with a diameter of 0.8 mm), which exists of a titaniumcapsule with radio-active

Jodium-125 (I-125).
I-125 is used in breast cancer surgery for several years. Main indications are localisation of non-palpable lesions, lesions treated with neo-adjuvant chemotherapy (NAC) with a possibility for pCR (complete pathological respons) and in large breast lesions (treated by breast-conserving-therapy) with a need for landmarking.
The main advantage of the use of I-125 markers is the fact that implnated seeds do not migrate or dislocate. Thereby providing a reliable localisation.
Further, the radio-active seeds can be implanted some time before surgery, to overcome logistical problems.
The disadvantage of localisation, as with guide-wire placement, is the risk for punction pneumothorax.

Study design

Patients in whom the pulmonologist indicated the need for surgical biopsy by means of VATS.
In stead of guide-wire placement and localisation a I-125 marker is placed:

- The pulmonologist decides the indication.
- The pulmonologist and radiologist do implant teh I-125 marker with a punction needle (under auspicien of the nucleair medicine specialist).
- The surgeon localises the I-125 marker by means of a probe during VATS and takes a biopsy.
- The pathologist removes the I-125 marker (conform the local protocol, under auspicien of the nucleair medicine specialist) and analyses the lesion.

Intervention

Implant of a I-125 marker (radio-active seed).

Study burden and risks

No increase of burden and risk compared to the common implant technique (guide-wire)

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

Lung lesion wthout a diagnosis with an indication for surgical biopsy

Exclusion criteria

No exclusion criteria

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2011
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL36464.008.11