Feasibility of an Electromagnetic Navigation System in a Standard Clinical Ultrasound Endoscopy Setting

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The goal of this study is to investigate the feasibility of the integration of an EMTS in a standard clinical EUS setting.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON39930

Source
ToetsingOnline

Brief title
EM Navigation in EUS

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
Non-small-cell lung carcinoma; lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electromagnetic Navigation, Electromagnetic Tracking System, Endoscopic Ultrasound

Outcome measures

Primary outcome

The primary study parameter is the accuracy of the EMTS. This is measured as

the orthogonal distance between the position of the US plane in which an

anatomical landmark is visualized and the corresponding landmark on the CT

data.

Secondary outcome

The secondary objective is to determine the usability of the navigation system.

This is achieved by letting the physician fill out an SUS directly after the

EUS procedure.

Study description

Background summary

Treatment planning and prognosis of Non-Small-Cell Lung Carcinoma (NSCLC) are highly dependent on preoperative staging. Endoscopic Ultrasonography guided Fine Needle Aspiration (EUS-FNA) is the preferred staging method.
However, pulmonary physicians have experienced difficulties getting proficient in this procedure. This is because the endoscopic image is very poor, which leads to the Ultrasound (US) image to be the only input for orientation. The interpretation of these images proves to be difficult.
Using an Electromagnetic Tracking System (EMTS) to track the patient*s and the endoscope*s position, it is possible to display the endoscope*s position and orientation relative to the patient in a volumetric anatomical map, based on a CT scan. This provides the physician with additional information which aids the (novice) physician in interpreting the US image and which can lead to a reduction of procedure time.

Study objective

The goal of this study is to investigate the feasibility of the integration of an EMTS in a standard clinical EUS setting.

Study design

This study is designed as a pilot study.
A 3D anatomical map is produced of patients who are planned for non-emergency EUS-FNA and who have signed informed consent. This map is based on a (CE-/PET-) CT scan which is already available, so no additional CT scans are required for this study.
Prior to the EUS procedure three Electromagnetic (EM) position sensors are taped to the subject and a custom designed EM sensor tool is introduced in the working channel of the EUS endoscope. Using an EMTS the position of the endoscope relative to the patient is continuously calculated and displayed on an additional screen. By visualizing several anatomical landmarks (lymph nodes) in the US plane and comparing the position of the US plane to the same landmarks on the CT data the orthogonal distance can be calculated. This is a measure for the accuracy of the system. Subsequently the planned FNA is performed.
Directly afterwards the physician fills out a Standard Usability Survey (SUS).

Study burden and risks

The risk for adverse events is negligible in this study. As long as the exclusion criteria are maintained, the addition of the electromagnetic navigation system to the EUS-FNA procedure does not pose any kind of threat to the subject.
The burden of this study to the subject consists of a prolongation of procedure time. Although the introduction of the endoscope in the esophagus can be experienced as annoying, most patients are not bothered by its presence once it is inserted. A lengthening of procedure time would thus not result in an increase of burden to the subject. If for whatever reason the subject does experience the procedure as very uncomfortable he can indicate this during the procedure. In consultation with the physician the procedure can then be stopped or shortened, by directly continuing with the FNA. The physician can also make this decision independently.

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

- Candidate for non-emergency EUS
- Signed informed consent provided
- Subject above 18 years of age
- CT thorax/mediastinum available

Exclusion criteria

- Existence of a pacemaker or Automatic Implantable Cardioverter Defribillator (AICD)
- Any subject whose medical condition implies that prolongation of the EUS procedure would have obvious adverse effects
- Obesity (Body Mass Index (BMI) > 30)
- Subjects with significant metal implants including, but not limited to, bone plates and bone screws near the mediastinum.
- Subjects with chest wall deformities (Pectus excavatum, pectus carinatum)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2013
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	Electromagnetic tracking system
Registration:	No

Ethics review

Approved WMO Date:	06-06-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	27-08-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL42599.044.13