Diffusion Weighted Magnetic Resonance Imaging To Differentiate In Thymus Pathology: A Pilot Study

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The aim of the study is to create and optimize a DWI MRI scan protocol to assess thymic masses.

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

Summary

ID

NL-OMON40543

Source
ToetsingOnline

Brief title
DWI to differentiate in thymus pathology

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
Follicular hyperplasia, Thymoma, Thymus

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diffusion weighted imaging, Thymoma

Outcome measures

Primary outcome

The main objective of this study is to create and optimize a DWI MRI scan

protocol

Secondary outcome

The second objective is to assess if DWI can differentiate between different

malignant and benign thymic masses and to asses of DWI MRI can accurate

determine the invasiveness of a thymoma.

Study description

Background summary

By the increased use of Computed Tomography (CT) of the chest more asymptomatic masses in the anterior mediastinum are found by coincidence. Asymptomatic thymic masses found by coincidence in patients without Myasthenia Gravis account for 42% in this population. Differentiation between malignant and benign masses on a CT can be difficult. With the development of minimal invasive surgery clinicians easier tend to a surgical resection. Because of this some patients undergo a surgical procedure for benign diseases. Diffusion Weighted Imaging (DWI) is a new technique that analysis the differences in the cellular structures. DWI could have additive value to CT and without the need for potentially harmful ionising radiation and nephrotoxic contrast agents required for CT imaging. Furthermore due its suburb contrast resolution.

Study objective

The aim of the study is to create and optimize a DWI MRI scan protocol to assess thymic masses.

Study design

A prospective, single center pilot study.

Study burden and risks

MR sequences have a very low rate of side effects. No MR contrast agent will be used for the assessment of the masses in the anterior mediastinum. The DWI MRI can be arranged on the same day they will be hospitalized for preoperative screening. This means that no extra hospital visit is needed. There is no known risk of MRI in pregnancy, however as a precaution MRI is not recommend during pregnancy. The MRI scan will take 10 minutes longer than regular MRI of the thorax due to these additional sequences (in total 45 minutes). However for this study population the treatment will not be altered on the outcome of the DWI MRI.

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 >18 years old, not pregnant
• All willing patients must provide written informed consent, agree to comply with the protocol;
• Suspected for an anterior mediastinal mass arising from the thymus and accepted for robotic thymectomy

Exclusion criteria

• Patients< 18 years old
• Patients with contraindications for MRI; metal impants, pacemakers, insulin pumps and nerve stimulators
• Claustrophobia

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-07-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	28-02-2014
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-05-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL45378.068.13