Diffusion-weighted whole-body imaging with background body signal suppression (DWIBS) at different magnetic field strengths in healthy volunteers

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The aims of this study are 1) to examine which magnetic field strength (1.0, 1.5, or 3.0 T) 2) in combination with which fat-suppression technique (STIR or SPIR/SPAIR) results in the best DWIBS images, 3) to detemine which respiration technique...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON31117

Source
ToetsingOnline

Brief title
DWIBS at different magnetic field strengths

Condition

- Other condition
- Lymphomas NEC
- Lymphomas NEC

Synonym
lymph node cancer, Malignant lymphomas

Health condition

Het betreft onderzoek naar beeldkwaliteit en normale lymfeklieren bij gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,MDPhD stipendium UMC Utrecht

Intervention

Keyword: Diffusion, Lymph node, Magnetic resonance imaging

Outcome measures

Primary outcome

1 a) Image quality of DWIBS obtained at different magnetic field strengths and with different fat-suppression techniques: average apparent contrast-to-noise ratio's with corresponding standard deviations of DWIBS-images obtained at 1.0 T, 1.5 T, and 3.0 T and with different fat-suppression techniques (STIR versus SPIR/SPAIR) will be compared

1 b) Image quality of three respiration techniques in DWIBS of the liver: image quality on a scale of 1 (poor) to 5 (very good) of breathhold, "respiratory triggered, and free breathing scanning will be compared

2) A mean ADC with SD will be calculated for non-malignant (normal) lymph nodes.

Secondary outcome

The number of non-analyzable images will be registered.

Study description

Background summary

Malignant tumors are the second most common cause of death and are responsible for more than 12.5% of all deaths worldwide. Computed tomography (CT), positron emission tomography (PET) and the recently introduced combined PET/CT play an inportant role in staging and follow-up of malignancies. Unfortunately these examinations are accompanied with a significant amount of radiation, which can induce second malignancies on the long term. Moreover, the intravenous application of a contrast agent necessary for CT may cause allergic reactions and may cause contrastnephropathy. New magnetic resonance imaging (MRI) techniques offer an alternative way for staging and follow-up of cancers, including the malignant lymphomas. Whole-body MRI (WB-MRI), including diffusion-weighted sequences (DWIBS), is a radiation-free method which allows imaging of the body with excellent soft tissue contrast in a examination, without the application of a contrast agent. The optimal parameters for the recently developed DWIBS-technique, however, have not been established yet. It is also unknown which lymph nodes on DWIBS images can be classified as non-malignant (normal) and which lymph nodes on DWIBS images can be classified as malignant.

Study objective

The aims of this study are 1) to examine which magnetic field strength (1.0, 1.5, or 3.0 T) 2) in combination with which fat-suppression technique (STIR or SPIR/SPAIR) results in the best DWIBS images, 3) to detemine which respiration technique results in the best image quality in DWIBS of the liver (breathhold scanning, respiratory triggered scanning, or free breathing scanning), and 4) to determine the apparent diffusion coefficient (ADC) of non-malignant (normal) lymph nodes.

Study design

This will be a unicenter, prospective, diagnostic cohort study (timeschedule: 2 months). 15 volunteers will undergo a DWIBS-scan in each of the 3 different scanners (1.0 T, 1.5 T, and 3.0 T MRI-scanners). Measurements will be made on the obtained DWIBS-images.

Study burden and risks

Every volunteer will undergo 3 MRI-scans, with each MRI-scan being performed in another scanner. The volunteer has to try to lie still during scanning. The first MRI-scan takes approximately 60 minutes. During this scan, the volunteer has to hold his/her breath during 20 seconds, which will be repeated 6 times.

The remaining two MRI-scans will each last approximately 45 minutes. Cumulative duration is approximately 2* hours (1 x 60 + 2 x 45 minutes). All MRI-scans are completely non-invasive and without any side-effects.

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

- male or female volunteers
- age: 18 years and older
- the participant must willingly give written informed consent prior to the start of the study

Exclusion criteria

- volunteers who underwent surgery in the past
- volunteers who had a malignancy in the past
- volunteers who have been or are suffering from a chronical inflammation or infection
- volunteers using medication at present
- volunteers who suffered from a transient infection within the past two months
- volunteers with symptoms possibly indicating an active inflammation or infection (e.g. fever, chills, night sweats, malaise, weight loss, fatigue, rhinorrhoe, coughing, throat ache, nausea, vomiting, diarrhea, etc.)
- volunteers with a general contraindication for MRI (including cardiovascular pacemakers, claustrofobia)
-volunteers who don't want to be informed about incidentally discovered lesions
-employees of the Department of Radiology of the UMC Utrecht

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):	14-11-2007
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	21-08-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	08-01-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL17270.041.07