Imaging and angiogenesis of malignant lymphoma with dynamic MRI, H-MRS, P-MRS and FDG-PET/CT for staging, mid treatment assessment and outcome.

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Evaluation of the vascularisation of malignant lymphoma and its change during therapy with DCE-MRI. Furthermore evaluation of metabolite concentration ratios and absolute measurements made with MRS techniques as a measurement of vascularisation and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lymphomas non-Hodgkin's unspecified histology
Study type	Observational invasive

Summary

ID

NL-OMON35043

Source
ToetsingOnline

Brief title
CILA

Condition

- Lymphomas non-Hodgkin's unspecified histology

Synonym
cancer of the lynphatic system, Malignant lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W,NIH

Intervention

Keyword: angiogenesis, DCE-MRI, Malignant lymphoma, MRS

Outcome measures

Primary outcome

Correlation between DCE-MRI and MVD of malignant lymphoma tissue. Correlation between MRS and response to treatment. Correlation between MRS and vascularisation.

Secondary outcome

Evaluation of the correlation between FDG-PET/CT parameters, DCE-MRI parameters and the changes during treatment.

Study description

Background summary

Malignant lymphoma constitute a heterogeneous group of diseases, derived from either B- or T-cell lymphocytes at different stages of maturation and with different pathogenic pathways and patterns of molecular alterations. Both histology and the extend of the disease determines the choice of therapy. Treatment often leads to remission but not always to cure. Within each histological entity biological behaviour can be very diverse. In order to improve treatment results, identification of risk profile and adequate evaluation of the tumour is necessary. Evidence of the role of angiogenesis in cancer, such as malignant lymphoma, is manifold. Microvessel density (MVD) in malignant lymphoma correlates with malignancy grade and pro-angiogenetic factors such as biochemical vascular endothelial growth factor (VEGF) can function as an independent prognostic factor. From previous research with other tumours dynamic magnetic resonance imaging with contrast (DCE-MRI) correlates with perfusion, hence metabolism. MRS techniques enable the in vivo measurement of metabolic aspects of tissue. H MRS demonstrates that that the signal of choline is a hallmark of (agressive) tumour growth. P MRS findings correlate with tumour perfusion and, hence with tumour angiogenesis.
Treatment response is currently monitored by [18F]-fluorodeoxyglucose positron

emission tomography fused with computed tomography (FDG-PET/CT). A disadvantage being the radiation burden with its risk of inducing secondary malignancies in the long term.

Study objective

Evaluation of the vascularisation of malignant lymphoma and its change during therapy with DCE-MRI. Furthermore evaluation of metabolite concentration ratios and absolute measurements made with MRS techniques as a measurement of vascularisation and predictor of response to treatment.

Study design

Prospective, observational non-randomized cohort investigation.
When there is no treatment option the patient will only get one DCE-MRI in combination with MRS. A blood sample will be taken every three months to determine the VEGF.
When a patient is considered for treatment an MRI exam will be acquired prior to treatment, after 3 cycles of chemotherapy and after completion of treatment. This exam will include a DCE-MRI exam and a 31P and 1H MR spectroscopy. For practical reasons 31P MRS will only be performed on 10 patients with a superficial lymph node mass. Blood withdrawal will take place prior to every cycle of chemotherapy and after completion of treatment.

Study burden and risks

Patients will undergo a maximum of three DCE-MRI and a maximum of three MRS examinations. This implies at the upmost 3 additional journeys to the hospital. An intravenous canula will be placed for the administration of MRI-contrast, Gadolinium, during the DCE-MRI examinations. In addition there will be several blood withdrawals. If there is no treatment option blood will be withdrawn every 3 months. If the patient is being treated it will be withdrawn prior to every cycle of chemotherapy and after termination of the treatment. Whenever possible in combination with the insertion of a canula for DCE-MRI or regular blood withdrawal. A possible risk can be caused by Gadolinium although it is relatively safe and being used in humans for many years. Possible side effects which can occur are a warm sensation throughout the body, dry mouth and/or the urge to urinate. These are considered to be minor and subdue mostly quick. There is a small risk of an allergic reaction such as itching, red skinlesions or sneezing. Although rare a more severe allergic reaction can occur such as mucosal swelling, shortness of breath and/or drop in blood pressure. These reactions can be adequately reversed with quick administration of medication.

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

• >= 18 years.
• WHO performance status: 0-3 (see appendix 1)
• Karnofsky score >= 80 (see appendix 2)
• Biopsy proven de novo or relapsed malignant lymphoma of any histological subtype. Relapsed patients who participated in this study during an earlier line of treatment may be re-entered in the study when fulfilling the inclusion criteria.
• Sufficient biopsy material present to perform anti-CD34 staining and subsequent MVD assessment.

Exclusion criteria

• Other active malignancy (less than 5 years in complete remission) except skin carcinoma (non-melanoma).
• HIV positive patients.
• Patients with contra-indications for contrast enhanced MR exams:
o Claustrophobia,
o Cardiac pacemaker or pacemaker wiring in situ,
o Cerebral clips or metal artificial cardiac valves,
o Ossicle prosthesis
o Renal failure
• Pregnancy or breastfeeding .
• No staging FDG-PET/CT available.
• Inability of giving informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-09-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	17-06-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL30575.091.10