Test-retest repeatability of quantitative radiomics features of FDG PET/CT studies in patients with diffuse large B cell lymphoma

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

Summary

ID

NL-OMON48134

Source
ToetsingOnline

Brief title
Radiomics TRT

Condition

- Lymphomas non-Hodgkin's B-cell

Synonym
diffuse large B cell lymphoma, lymph node cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: [18F]FDG, lymphoma, radiomics, repeatability

Outcome measures

Primary outcome

The test-retest repeatability of radiomics features with different image

reconstruction settings.

Secondary outcome

not applicable

Study description

Background summary

Diffuse large B-cell Lymphoma (DLBCL) is an agressive form of lymph node cancer with a variable prognosis. Up to 40% of the patients do not respond well to first-line R-CHOP treatment. Current prognostic measures do not accurately predict therapy failure whereas the need for such a prognostic marker is increasing due to new promising treatment options. Good prognostic markers could help identify the patiënt with a high risk of failure after R-CHOP treatment. Pheno-and genotypic heterogeneity likely explains why pagtients and even lesions within the same patient, respond differently to therapy. Quantitative image features from whole body FDG PET-CT capture metabolic heterogeneity at a lesional and patient basis. The spectrum of such features (many different parameters covering e.g. shape, metabolice active volume, heterogeneity) is called radiomics. Recently,studies examaning radiomics of PET-based tumor phenotyping have shown that radoimics features have prognostic potential.

Study objective

At the moment it is unknown which radiomics features are robust against variations in image characteristics. The objective of this study is to check the robustness of radiomics features, and to investigate wheter specific pre- and postprocessing routines should be performed to improve the robustness. We will check this by scanning 20 patients on two seperate occasions within one

week.

Study design

In this monocenter observational study with invasive measurements patients with diffuse large B-cel lymphoma will be included. All patients will undergo the current standard diagnostic procedure including an [18F] FDG PET scan. The second [18F]FDG PET scan will be perfomed for this study within one week after the first scan. There is no further follow-up period. We expect to include the total number of 20 patients in 12 months.

Study burden and risks

During this study, all patients will receive a venous cannula for tracer injection. This might cause transient intravenous site discomfort. Patients will undergo PET imaging twice. A PET scan is a regular diagnostic imaging technique. Each study will be conducted in compliance with the radiation safety guidelines of the department. However, this imaging technique has its risks as patients are exposed to radiation. The first [18F]FDG PET/CT scan is standard of care for these patients and is responsible for 3.5 mSv from the administered tracer [18F]FDG and 3 mSv from the low-dose CT scan. The radiation burdon for the retest [18F]FDG PET/CT is 6.5 mSv. The total sum of radiation burdon per patient for a complete set of test-retest studies will be approximately 13 mSv. Participating in this study will result in an extra radiation burdon of 6.5 mSv compared to the standard of care. This is to the same order of magnitude as the annual natural background radiation in various parts of the world(Netherlands Commission on Radiation Dosimetry, 2016)

In a general population of age 65, a dose of 6.5 mSv is estimated to increase the lifetime change of developing fatal cancer with 0.02%, in addition to a baseline change of 44.9% for males and 37.5% for females (XrayRisk, 2018). The study population has a decreased survival (Sehn et al., 2015), while the possible hazard of cancer induction by radiation is only to be expected after decade(s) post exposure. Consequently, the actual increase in chance of developing a fatal cancer for these patients is thus only a fraction of the percentage mentioned above. In the light of this scientific merit the investigators therefore consider the additional radiation burden acceptable, balancing ethical considerations with the minimum number required to obtain reliable information.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patient age 18 years or older
- Diagnosed with diffuse large B cell lymphoma
- At least one tumour with diameter > 3cm (to minimize partial volume effects)
- Able to remain supine for 60 minutes in the PET-CT scanner
- Written and signed informed consent

Exclusion criteria

- Chemotherapy in the past 4 weeks
- Multiple malignancies
- Pregnant or lactating patients
- Metal implants (e.g. pacemakers)
- Any medical, physiological or social condition that may interfere with the subject*s safety and participation in the study, will lead to exclusion from this study

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):	03-02-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	21-06-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL69524.029.19