Perfusion PET Sarcoma: Feasibility of tumor perfusion quantification with Gallium-68-citrate PET/CT in sarcoma and radiotherapy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON34488

Source
ToetsingOnline

Brief title
Perfusion PET Sarcoma

Condition

- Soft tissue neoplasms malignant and unspecified

Synonym
Sarcoma. Soft tissue tumor

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: Afdeling Nucleaire geneeskunde

Intervention

Keyword: Feasibility, Gallium-68-Citrate, Perfusion PET, Sarcoma

Outcome measures

Primary outcome

(1) Feasibility of the technique. (2) Increased knowledge on vascular response

of tumor to radiotherapy, including the difference between MLS and non-MLS.

Secondary outcome

(1) Technical optimization of the procedure. (2) new (research) approaches for

personalised treatment strategies.

Study description

Background summary

Tumor vasculature is an important factor in biological response to treatment. Imaging of tumor perfusion both before and after treatment is difficult, and existing techniques have their merits and disadvantages. Diffusion and contrast enhanced perfusion weighted magnetic resonance (MR) imaging have shown some promising results, but MR is laborious, expensive, and difficult to quantify. Dynamic contrast enhanced computed tomography (ceCT) is quantitative, but yields a radiation dose for a limited field of view.
We propose an alternative method for visualization of tumor perfusion in humans, using the Gallium-68-citrate perfusion tracer and positron emission tomography (Perfusion-PET) imaging. This dynamic and 3-dimensional technique is readily available, and is able to (a) quantify the regional blood volume in tumor tissue, and (b) quantify leakage to the extracellular space as a parameter of vascular permeability. These parameters may be indicative of the treatment outcome of radiotherapy, and may be of future value for treatment selection or adaptation.

Study objective

The study aims (1) to determine the feasibility of Perfusion-PET with Gallium-68-citrate, prior to and during radiotherapy, and (2) to better

understand the process of vascular response of tumor to radiotherapy, including differences between MLS and non-MLS. Secondary aims are to optimize the procedure, and to derive new (research) approaches for personalised treatment strategies.

Study design

Twenty (20) patients who have been referred for preoperative radiotherapy on a primary sarcoma (any site) will be asked to undergo perfusion-PET as a study procedure. This group will be divided in 2 subgroups: an MLS-group (n=10) and a non-MLS group (n=10). The MLS patients will serve as a so called positive control: good vascularization at diagnosis and a shut-down during radiotherapy. The perfusion phenomena in patients with non-MLS histologies are unpredictable and they will be regarded each as a study subject by themselves.
The perfusion-PET will be performed prior to radiotherapy and after the 8th, the 16th and the 25th fraction of external beam radiotherapy.
Changes in tumor blood volume and extravasation will be plotted against the number of fractions radiotherapy given. The images will be correlated with histopathology at the time of resection.

Study burden and risks

4x Intravenous administration of a (known to be safe) radioactive tracer, followed by a PET with lowdose CT scan, for a total
radiations exposure of maximum 6 mSv. Longer stay in the department of nucleaire geneeskunde for a maximum of 1 hour (after the radiotherapy treatment).

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 with primary untreated sarcomas referred for preoperative radiotherapy of any site (head and neck, trunk and chest wall, retroperitoneum and extremities); to be divided in a MLS and a non-MLS subgroup.
-Willing to undergo additional perfusion PET on the days of the planning CT scan and the days of the 8th, 16th and 25th fraction.
-Signed informed consent

Exclusion criteria

-Age < 18 years
-Pregnancy or laction
-Incapacitated subjects

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	28-10-2010
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL33439.031.10