Human Cerenkov Luminescence Imaging of Superficial In-Vivo Tumours after Administration of 18F-FDG

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON42215

Source
ToetsingOnline

Brief title
Feasibility of In-vivo Human Cerenkov Imaging

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Cancer, malignant tumours

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Afdeling Heelkundige Oncologische

Disciplines;NKI-AVL

Intervention

Keyword: 18F-FDG, Cerenkov, Imaging, In-Vivo

Outcome measures

Primary outcome

The main question is whether we ara able to image the uptake of 18F-FDG in a human tumour, in-vivo, with a stand alone EMCCD camera. The primary study parameter is if we can subjectively distinguish the tumour from the background.

Secondary outcome

Secondary study parameters are the signal to noise ratio between the tumour and healthy tissue. With that we take the actual uptake and the depth of the tumour into account.

Study description

Background summary

During tumour resection it is important to remove all the malignant tissue without compromising functional and cosmetic outcomes. To achieve this surgeons the surgeons should be able to distinguish malignant from healthy tissue. Several techniques are available to assist the surgeon in localizing the tumor. However, for the assessment of malignant versus healthy tissue the surgeon depends mostly on sight and tactile sense. For some tumours this is a difficult task. Especially when there is a disturbed anatomy and fibroses due to prior surgery or radiation.
To localize the tumor and to prevent positive resection margins a technique to visualize the tumor intraoperatively is of much value to the surgeon.

Cerenkov luminescence imaging (CLI) is a new technique that combines PET with optical imaging and has therefore the possibility to image tumours intraoperatively. Cerenkov radiation is a natural phenomenon that occurs when charged particles travel through a medium, faster than the speed of light in that particular medium. This also occurs with PET tracers in the human body.

The Cerenkov radiation is manifests in emitting a very small amount of photons that can be measured in a light tight area with a high sensitivity EMCCD Camera.

The combination of FDA approved tumour specific PET tracers with a high resolution mobile camera offers the possibilities to develop an image guided surgery device.

Study objective

The primary objective of this study is to proof the principle of imaging a tumour in-vivo, with Cerenkov radiation.
Furthermore we want to determine the difficulties and limiting factors for in-vivo CLI. Determine the SNR (Signal to Noise) and the Cerenkov radiation signal due to physiological uptake.

Study design

Observational pilot study

Study burden and risks

Based on the proceedings of this study we do not expect additional risks for the patient. For the purpose of this study the patients will have to undergo additional CLI in a light tight room. The CLI procedure will be non-invasive. Patients have to lie on an examination bed with the tumour uncovered presented to the camera. Multiple images will be made with acquisition time varying from 1 to 300 seconds. During the acquisition the imaged part of the body should not be moved. The maximum amount of time the additional imaging will take is 30 minutes. For this investigation no extra measures have to be taken for the patients.

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, older than 18 years, who will receive and 18F-FDG PET-CT scan and have a superficial tumour, <3 cm from surface, that shows sufficient uptake of 18F-FDG.

Exclusion criteria

Patient younger than 18 years.
Patients with a melanoma with a high melanin level.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2015
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	13-04-2015
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	NL52499.031.15