Non invasive imaging of [18F]HX4 with Positron-Emission-Tomography (PET) in Cervix Cancer.

Published: 28-03-2014
Last updated: 20-04-2024

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

Summary

ID

NL-OMON44375

Source
ToetsingOnline

Brief title
[18F]HX4 with PET-CT in Cervix Cancer

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cervix cancer

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO clinic
Source(s) of monetary or material Support: METOXIA

Intervention

Keyword: [18F]HX4, Cervix Cancer, PET-CT, Phase II trial

Outcome measures

Primary outcome

Primary endpoint: Tumor to background ratio of [18F] HX4 PET images.

Secondary outcome

Secondary endpoints:

- Overlap fraction of (for example) >50% max regions (i) before and during treatment (ii) in the time series.

- Define the optimal time point for HX4 imaging in Cervix cancer, based on the highest tumor to background ratio.

- Determine if there is a relationship between the SUVmax, SUVmean or tumor to muscle ratio in comparison to the amount of osteopontin in the blood, circulating CA-IX in the blood or the degree and presence of tumor tissue markers.

- Overlap fraction of (for example) >50% max regions between HX4-PET and FDG-PET pre-treatment or three months after treatment.

- Correlation of the SUVmax, SUVmean and tumor to muscle ratio in the [18F] HX4 PET images in comparison to local tumor recurrence and survival.

- Correlation of the SUVmax, SUVmean and tumor to muscle ratio in the [18F] HX4 PET images in comparison to Complete Remission rates at 3 months

Study description

Background summary

Tumor hypoxia is the situation where tumor cells are or have been deprived of oxygen. Hypoxic tumor cells are more resistant to radiotherapy and chemotherapy and more likely to develop metastasis. In Cervix cancer, tumor hypoxia is known to be an important prognostic factor for long term survival. [18F]HX4 is being developed as a diagnostic radiopharmaceutical for PET imaging to find a marker for hypoxia that can be used in standard clinical practice. Current hypoxia tracers lack reliable image quality and kinetics. Because of the short half life and clearance, we expect that [18F]HX4 will have a higher tumor to background ratio than current nitro-imidazole hypoxia markers such as [18F]-misonidazole. In a recent phase 1 clinical study from van Loon et al1, PET-imaging with [18F]HX4 was feasible without any toxicity. The clinical use of a reliable, non-invasive and easy to use hypoxia imaging agent could allow selection of patients most likely to benefit from hypoxia modifying therapies.

Study objective

The aim of this study is to (i) determine non-invasive visualisation of tumour hypoxia with [18F] HX4 PET imaging in cervix carcinomas; (ii) correlate [18F] HX4 PET images with blood and tissue markers for hypoxia; (iii) investigate the quality and optimal timing of [18F] HX4 PET imaging; (iv) compare [18F] HX4 PET uptake with [18F] FDG PET uptake before treatment and (v) correlate the SUVmax of [18F] HX4 PET imaging and delta SUVmax with clinical outcome at 3 month after treatment.

Study design

A non-randomized, open label trial. Eligible patients with squamous cell carcinoma, adenocarcinoma or adenosquamous carcinoma (FIGO stage IB * IVA), to be treated with curative radiation treatment either or not combined with concurrent chemotherapy or deep hyperthermia are included. 4.1 Before treatment A standard clinical [18F]FDG PET-CT will be performed for the radiotherapy planning. After a minimum time interval of 24 hours, baseline [18F]HX4 PET scans will be performed: Based on the phase I trial1 444 MBq (12 mCi) [18F]HX4 is administrated via a bolus IV injection. The first image acquisition is started together with the administration of [18F]HX4 (30-40 min dynamic). Static scans are acquired at 90 min, 180 min and 240 min p.i.* 4.2 Treatment Radiation treatment (either or not combined with chemotherapy or hyperthermia) will be performed according to the institutional protocol. During treatment [18F]HX4 scans (dynamic, 90, 180 and 240 min p.i.*) will be repeated after radiotherapy treatment with 20 ± 4 Gy (approximately two weeks), by administrating 444MBq (12mCi) [18F]HX4 via a bolus IV injection. 4.3 Follow up: according to the institutional protocol.

Study burden and risks

all patients will be monitored closely during and after administration of the labeled [18F]HX4 .The proposed dosis [18F]HX4 is chosen based on the results of the phase I trial with [18F]HX4. In view of previous experiences wtih [18F]HX4, conventional FDG-PET CT an other nitroimidazole drugs, we expect no unforseen 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

-Histologically confirmed cervix carcinoma (squamous cell carcinoma, adenocarcinoma or adenosquamous carcinoma)
-WHO performance status 0 to 2
-Scheduled for primary curative surgery or radiotherapy (either or not combined with chemotherapy or hyperthermia)

- No previous surgery to the cervix
- No previous radiation to the cervix
- The patient is willing and capable to comply with study procedures
- 18 years or older
-Written informed consent before patient registration;Group A:
-FIGO stage IB, minimal tumour diameter 2cm.;Group B:
- FIGO stage IB (minimal tumour diameter 2 cm) - IVA

Exclusion criteria

-recent (< 3 months) myocardial infarction
-uncontrolled infectious disease
-pregnant or breast feeding and/or not willing to take adequate contraceptive measures during the study

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2015
Enrollment:	38
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Radiolabelled HX4 with 18 Fluor
Generic name:	[18F]HX4

Ethics review

Approved WMO Date:	28-03-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-09-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-09-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-10-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-07-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR2014-000224-17-NL
ClinicalTrials.gov	NCT02233387
CCMO	NL48115.068.14