Prognostic value of Fluorine-18 3-deoxy-3-fluorothymidine ([18F]FLT) uptake in resectable liver metastases of colorectal cancer

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1. to investigate the prognostic relevance of [18F]FLT uptake in resectable liver metastases of patients with colorectal cancer, in addition to existing prognostic indices with respect to disease-free survival; 2. in chemonaive patients, to validate...

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

Summary

ID

NL-OMON36536

Source
ToetsingOnline

Brief title
[18F]FLT liver metastases of colorectal cancer

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
bowel cancer, colorectalcancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Center for Translational Molecular Medicine

Intervention

Keyword: [18F]FLT PET, colorectal cancer, liver metastases

Outcome measures

Primary outcome

prognostic accuracy of [18F]FLT uptake in liver metastases with respect to

patient outcomes (DFS),

Secondary outcome

prognostic accuracy of [18F]FLT uptake vs. existing prognostic indices with

respect to patient outcomes (DFS).

Study description

Background summary

One-third of colorectal cancer patients have liver metastases at presentation, and 25% develop them after primary surgery. Patient management is dictated by technical resectability, residual liver function and absence of extrahepatic metastases. A Dutch multicentre ZON-MW study showed that preoperative [18F]FDG PET (by showing additional dissemination) reduces futile surgery by 38%. Still after surgery, outcome is highly variable (5 yrs survival 30-50%), and prognostic indicators beyond TNM staging are clearly needed.
With new systemic therapies emerging, biomarkers are needed to adapt (multimodality) therapy to the biological tumour profile of individual patients. Proliferation markers are variably successful, perhaps due to heterogeneity (spatial [within tumours] and/or temporal [differences between primary vs. metastatic]). Conceptually, the S-phase fraction related Fluorine-18 3-deoxy-3-fluorothymidine ([18F]FLT) PET signal preoperatively adds these spatial and quantitative dimensions.

Study objective

1. to investigate the prognostic relevance of [18F]FLT uptake in resectable liver metastases of patients with colorectal cancer, in addition to existing prognostic indices with respect to disease-free survival;

2. in chemonaive patients, to validate the association between standard histopathological proliferation markers in liver metastases and [18F]FLT uptake.

Study design

observational multicentre cohort study

Intervention

[18F]FLT PET(-CT).

Study burden and risks

benefit and group relatedness: single [18F]FLT PET- CT scan, yielding 4.4 mSv for a typical PET-CT acquisition. During the study, [18F]FLT PET studies will not be used for patient management.

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

*technically resectable liver metastases at the time of hepatic recurrence diagnosis
*written informed consent

Exclusion criteria

*claustrophobia prohibiting PET-scanning
*systemic cancer therapy within 3 months prior to PET
*largest liver metastasis <2 cm

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):	19-05-2011
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	05-07-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-09-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-09-2011
Application type:	Amendment
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
EudraCT	EUCTR2009-017150-12-NL
CCMO	NL29807.029.10