Induction of hypoxia following radiofrequency ablation of liver tumors.

Published: 24-11-2010
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To assess whether radiofrequency ablation in the liver is associated with hypoxia in the rim of the induced necrosis.

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

Summary

ID

NL-OMON36653

Source
ToetsingOnline

Brief title
Radiofrequency ablation and hypoxia

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
liver cancer, liver tumor

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hypoxia, liver metastasis, liver tumor, radiofrequenty ablation

Outcome measures

Primary outcome

Primary outcome measure: The endpoint of this study is the presence (or absence) of hypoxia (defined as demonstrable FAZA uptake) in the necrotic rim induced by RFA.

Secondary outcome

not applicable

Study description

Background summary

Surgical resection for colorectal liver metastases is applicable in only 15-30% of patients. Thermal destruction therapies such as radiofrequency ablation (RFA) use heat to destroy tumor tissue by inducing coagulative necrosis. This treatment modality is widely used for treatment of non-resectable colorectal metastases confined to the liver and may provide tumor clearance and increase life-expectancy. Nonetheless, recent articles on this topic revealed that local peri-lesional recurrences from colorectal metastases occur in up to 60% of cases.
In our preclinical work, we tried to elucidate the role of RFA on residual micrometastases. Recently, we have demonstrated in two different preclinical models that RFA accelerates the outgrowth of colorectal liver metastases located at the rim of the induced necrosis. Strikingly, the location of the accelerated tumor outgrowth is characterized by areas of hypoxia. These results show the role of hypoxia in tumor growth acceleration following RFA and may provide an initial explanation for the high local recurrence rates following RFA in patients. Until now, no clinical data are available on the role of hypoxia in local recurrences following RFA in the liver. With the research proposed, we will assess whether radiofrequency ablation in the liver is associated with hypoxia in the rim of the induced necrosis.

Study objective

To assess whether radiofrequency ablation in the liver is associated with hypoxia in the rim of the induced necrosis.

Study design

Observational descriptive study, with head-to-head comparison of pre-RFA and post-RFA uptake.

Study burden and risks

Double [18F]FAZA PET-CT scans, yielding two times 2.5 mSv for a typical FAZA PET, low dose-CT 0.9 mSv/ acquisition. During the study, [18F]FAZA PET studies will not be used for patient management. To compare, the natural background radiation dose in the Netherlands is 2-2.5 mSv per year.
Our goal is to perform the [18F]FAZA PET-CT scans in 10 patients, which will take approximately 1 year. Nonetheless, an interim analysis will be performed after 3 patients, which will lead to a decision to continue or terminate the study.

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 liver tumor(s) treated with percutaneous RFA
*Age > 18 years
*Written informed consent

Exclusion criteria

*Open RFA procedure for liver tumor by the surgeon
*Claustrophobia prohibiting PET-scanning

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):	18-04-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	24-11-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-02-2012
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
CCMO	NL33113.029.10