A phase II, open label, non-randomized, multi-center, pilot, efficacy study of [F-18]RGD-K5 positron emission tomography (PET) as a tool to monitor response to an anti-angiogenic drug

Published: 22-02-2010
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The primary objective for this study is:• To explore the usefulness of [F-18]RGD-K5 PET/CT to predict efficacy or early response toAvastin® (the anti-angiogenesis drug) plus chemotherapy treatment before the full courseof treatment is completedThe...

Ethical review	Approved WMO
Status	Pending
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON34945

Source
ToetsingOnline

Brief title
[F-18]RGD-K5

Condition

- Metastases

Synonym
colorectal liver metastases

Research involving
Human

Sponsors and support

Primary sponsor: Siemens Molecular Imaging Biomarker Research
Source(s) of monetary or material Support: Siemens Molecular Imaging (SMI)

Intervention

Keyword: [F-18]RGD-K5, bevacizumab, colorectal liver metastases, PET/CT

Outcome measures

Primary outcome

The primary objective for this study is:

• To explore the usefulness of [F-18]RGD-K5 PET/CT to predict efficacy or early

response to

Avastin® (the anti-angiogenesis drug) plus chemotherapy treatment before the

full course

of treatment is completed

Secondary outcome

The secondary objective for this study is:

• To gain experience with [F-18]RGD-K5 PET/CT in order to improve the study

design

and conduct of future studies

Study description

Background summary

Title:
A PHASE II, OPEN LABEL, NON-RANDOMIZED, MULTI-CENTER, PILOT, EFFICACY STUDY OF [F-18]RGD-K5 POSITRON EMISSION
TOMOGRAPHY (PET) AS A TOOL TO MONITOR RESPONSE TO AN ANTI-ANGIOGENIC DRUG

Protocol Number: K5-101
Date: 22 June 2009 FINAL VERSION

Design:
An open label, non-randomized, uncontrolled, single group assignment, pilot efficacy study

The participation of the NKI/AVL will focus on the inclusion of 10 patients met colorectal liver metastases.

Study objective

The primary objective for this study is:
• To explore the usefulness of [F-18]RGD-K5 PET/CT to predict efficacy or early response to
Avastin® (the anti-angiogenesis drug) plus chemotherapy treatment before the full course
of treatment is completed

The secondary objective for this study is:
• To gain experience with [F-18]RGD-K5 PET/CT in order to improve the study design
and conduct of future studies

Study design

An open label, non-randomized, uncontrolled, single group assignment, pilot efficacy study

Approximately forty (40) patients with non-squamous non-small cell lung cancer, metastatic breast cancer,
metastatic colon or rectum cancer who will receive chemotherapy plus Avastin®. This allows for
approximately 30 evaluable patients to complete this study at approximately four to eight sites internationally.

The NKI/AVL will focus on the inclusion of patients met colorectal liver metastases.

Study burden and risks

Very limited:

1. RGD-K5 presents no known risks either from preclinical studies in cell lines and animals or from clinical investigations of this compound in humans. A safety profile of [F-18]RGD-K5 was obtained from our exploratory study in

humans. Also, there are no adverse events reported for structurally similar compounds to RGD-K5 that have been investigated in human studies. Based on the findings obtained from pre-clinical evaluation and clinical testing in humans, and the very low chemical mass and excellent purity profile of [F-18]RGD-K5 to be administered as a single dose, [F-18]RGD-K5 presents no anticipated risks for this agent in humans.
The [F-18]RGD-K5 radiation dosimetry estimates derived from the human biodistribution study indicates the radiation
dosimetry to be similar to many other radiodiagnostic agents, and does not represent any undue risk.

2. In each patient included at the NKI/AVL the borders of one liver lesion will be marked before start of the neo-adjuvant chemotherapy. The punction the radiologist needs to perform to achieve this, implies a very limited risk of bleeding and infection.

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

• Patient is >18 years and male or female of any race / ethnicity
• Patient provides written informed
consent and willing to comply with protocol requirements
• Patient must be scheduled to receive chemotherapy treatment(s) plus Avastin® for their cancer care; treatment management will be made by treating medical oncologists (According to the package insert for Avastin®, it is administered as an IV infusion every 3 weeks for non-squamous non-small cell lung cancer, and every 2 weeks for metastatic breast cancer, colon or rectum cancer)
• Patient will be scheduled to have a clinical [F-18] FDG-PET/CT or diagnostic CT pretreatment, and after the fourth but before the fifth Avastin® treatment

Exclusion criteria

• Patient is not capable of complying with study procedures
• Female patient is pregnant or nursing
• Patient has a severe hepatic or renal disease as defined by previous medical history or abnormal renal and hepatic functions determined by lab results not within the following ranges, or in the opinion of the Investigator, the values are not acceptable for the patient to be included:
o AST (SGOT)/ALT (SGPT) <= 2.5 x institutional upper limits of normal
o Serum creatinine <= 2x institutional upper limits of normal
o BUN within 2x institutional upper limits of normal
• Patient has known hyper or hypo-coagulation syndromes. (e.g. Protein C, S deficiency, Hemophilia A/B/C, Factor-V Leiden, etc) or lab results are not within the following ranges, or in the opinion of the Investigator, the values are not acceptable for the patient to be included:
o Platelet counts of < 75 x 103/µL
• Patient has known sensitivity to any components of Avastin® such as recombinant human or humanized antibodies
• Patient has been involved in an investigative, radioactive research procedure or within 7 days and during the study participation period
• Patient will participate in experimental therapy procedures while participating in this clinical trial
• Patient has any other condition or personal circumstance that, in the judgment of the investigator, might interfere with the collection of complete data or data quality to achieve study objectives, or complete study and/or post-dose follow-up examinations

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2010
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	[F-18]RGD-K5
Generic name:	[F-18]RGD-K5

Ethics review

Approved WMO Date:	22-02-2010
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	12-05-2010
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
EudraCT	EUCTR2010-018874-19-NL
CCMO	NL30174.031.10