A PHASE 0 SINGLE MICRODOSE STUDY TO EVALUATE THE PHARMACOKINETICS/-DYNAMICS AND SPECIFIC TUMORTARGETING OF 124-I-F16SIP IN HEAD AND NECK CANCER PATIENTS

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To evaluate the tumor targeting performance of the human radiolabeled antibody 124I-F16SIP.To investigate pharmacokinetics/-dynamics of 124I-F16SIP, and to assess its uptake in tumor and normal tissues as obtained from the surgical specimen.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON32737

Source
ToetsingOnline

Brief title
F16SIP phase 0

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
head and neck cancer, head and neck squamous cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Philogen

Intervention

Keyword: 124I-F16SIP, Head and neck cancer, Phase 0, Tumor targeting

Outcome measures

Primary outcome

The tumor targeting performance of the human radiolabeled antibody 124I-F16SIP.

Pharmacokinetics/-dynamics of 124I-F16SIP, and its uptake in tumor and normal

tissues as obtained from the surgical specimen.

Secondary outcome

Dosimetric parameters for tumor, bone marrow and normal organs.

Study description

Background summary

The F16SIP is a fully human antibody fragment, capable of preferential localization around tumor blood vessels while sparing normal tissues. The formation of new blood vessels is a rare event in the adult (exception made for the female reproductive cycle), but is a pathological feature of most aggressive types of cancer. The study aims at determining the pharmacokinetics/-dynamics and specific tumor targeting properties of the F16 antibody in SIP format, labeled with the radionuclide 124I, in head and neck cancer patients.
An efficient accumulation of 124I-F16SIP on the tumor lesions may provide and incentive for both patient and clinical center to consider future therapeutic strategies on the patient, based on F16 derivatives (e.g., F16-IL2 or 131I-F16SIP).

Study objective

To evaluate the tumor targeting performance of the human radiolabeled antibody 124I-F16SIP.

To investigate pharmacokinetics/-dynamics of 124I-F16SIP, and to assess its uptake in tumor and normal tissues as obtained from the surgical specimen.

Study design

This is a phase 0 single microdose study of the tumor targeting human 124I-F16SIP monoclonal antibody, performed according to EMEA guideline CPMP/SWP/2599/02/Rev1.
It is a uncontrolled, open-label study in one clinical center. 5 head and neck cancer patients will be enrolled.
Single dose of 2 mg 124I-F16SIP labelled with up to 2 mCi (74 MBq) will be administered i.v. to consenting patients. Target localization will be analyzed by 3 PET/CT scans. Patients will be operated 7/8 days after infusion and the uptake of 124I-F16SIP in tumor and normal tissues present in the surgical specimen will be measured. The safety and tolerability of 124I-F16SIP will be assessed with laboratory tests, vital signs measurement and recoding of adverse events. Furthermore, the dosimetric parameters for the bone marrow will be investigated.

Intervention

Administration of a single injection of 2 mg 124I-F16SIP, i.v.

Study burden and risks

Patients are exposed to radioactivity, but this will be very low because of the low amount of radioactivity that will be used.
No adverse events are expected from the use of 124I-F16SIP.

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

1. Patients with previously untreated head and neck cancer scheduled for surgery
2. Histologically/cytologically confirmed diagnosis of cancer.

Exclusion criteria

1. 1. Chemotherapy, radiation, hormone therapy (with the exception of a gradual titration of LHRH agonists) or immunotherapy or participation in any investigational drug study within 4 weeks of study entry (6 weeks in case of prior nitroureas chemotherapy).
2. Prior radiation dose > 30% of bone marrow volume.
3. Presence of cirrhosis or active hepatitis.
4. Presence of serious cardiac (congestive heart failure, heart insufficiency > grade II NYHA, angina pectoris, myocardial infarction within one year prior to study entry, uncontrolled hypertension or arrhythmia), neurological or psychiatric disorders.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-08-2010
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	124I-F16SIP
Generic name:	124I-F16SIP

Ethics review

Approved WMO Date:	20-01-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-08-2010
Application type:	First submission
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	EUCTR2009-016036-12-NL
CCMO	NL29836.029.09