Imaging tumor angiogenesis using 18F-Fluciclatide PET/CT in patients with colorectal and pancreatic cancer.

Published: 04-03-2019
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Evaluating the feasibility of 18F-Fluciclatide PET/CT imaging of colorectal and pancreatic tumors.

Ethical review	Approved WMO
Status	Completed
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON54757

Source
ToetsingOnline

Brief title
18F-Fluciclatide tumor imaging.

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
bowel cancer, pancreatic cancer.

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: European Research Council grant

Intervention

Keyword: angiogenesis, PET/CT, tumor

Outcome measures

Primary outcome

Sensitivity/specificity of 18F-Fluciclatide.

Secondary outcome

Optimal imaging window of this tracer

Feasibility of responsemonitoring with this tracer

Study description

Background summary

In both colorectal and pancreas carcinoma treatment, neoadjuvant treatment protocol are used more frequently. As a consequence of this therapy, tumor shrinkage is seen and even in some cases resection of the primary tumor is not necessary.
However, using the current imaging modalities available (CT, MRI and PET/CT), tumor response monitoring to neoadjuvant therapy is challenging.
In this study, we propose tumor response monitoring using 18F-Fluciclatide. This new PET tracer targets integrins which are expressed on neoangiogensis associated with both colorectal and pancreatic tumors.

Study objective

Evaluating the feasibility of 18F-Fluciclatide PET/CT imaging of colorectal and pancreatic tumors.

Study design

Colorectal and pancreatic carcinoma patients will be asked to undergo one or two 18F-Fluciclatide PET/CT scan(s). This way, after resection, imaging findings can be correlated to integrin expression on the tumor resection specimen and the feasibility of response monitoring will be assessed.

Study burden and risks

Moderate. Since no adverse events have been observed from the use of this tracer before, we expect no allergic reactions.

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

Biopsy proven primary colorectal adenocarcinoma or suspected pancreatic ductal adenocarcinoma, as agreed on by multidisciplinary team;
No prior chemo(radio)therapy in rectal cancer patients.
Patients treated in the LUMC.
Before patient registration, written informed consent must be given according to ICH/GCP, and national/local regulations.

Exclusion criteria

Contraindication for PET (pregnancy, breast-feeding and severe claustrophobia);
Impaired renal function (creatinine clearance < 60 mL/min according to the Cockcroft-Gault equation or ureum < 2x ULN (Upper limit of normal);
Impaired liver function (ALAT, ASAT > 3 ULN or total bilirubin >2x ULN);
Known allergy to pABA (p-aminobenzoate sodium salt);
Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule;
Inability to tolerate lying supine for the duration of a PET/CT examination (~30min).

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-06-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	18F-Fluciclatide
Generic name:	18F-Fluciclatide

Ethics review

Approved WMO
Date: 04-03-2019

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 21-03-2019

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 10-04-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 14-05-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 01-10-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 29-10-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	31-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	08-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	22-05-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	EUCTR2018-003522-86-NL

Register	ID
CCMO	NL67454.058.18

Study results

Date completed: 23-05-2024

Actual enrolment: 4

Summary results
Trial ended prematurely