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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21459

Source
NTR

Brief title
18F-Fluciclatide tumor imaging

Health condition

Pancreatic cancer, colorectal cancer.

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: ERC Advanced grant

Intervention

Outcome measures

Primary outcome

Assess feasibility and sensitivity of imaging tumor angiogenesis in PDAC and colorectal adenocarcinoma, using 18F-Fluciclatide. When successful, the data of this study will allow for a larger trial.

Secondary outcome

To define the most optimal PET acquisition time interval after i.v. administration of 18F-Fluciclatide PET/CT;
To validate 18F-Fluciclatide as a clinical marker of angiogenesis by immunohistochemistry assessment of angiogenesis in PDAC and colorectal adenocarcinoma resection specimens.

Study description

Background summary

18F-Fluciclatide PET imaging in colorectal and pancreatic cancer detection.

Study objective

18F-Fluciclatide PET imaging can detect colorectal and pancreatic lesions.

Study design

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Intervention

18F-Fluciclatide PET scan

Contacts

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Eligibility criteria

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.
Patient scheduled to undergo surgery;
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 CockcroftGault 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 conditionpotentially 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 type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status:	Pending
Start date (anticipated):	01-04-2019

Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	17-03-2019
Application type:	First submission

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
NTR-new	NL7605
Other	METC LUMC : P18.210

Study results