FAPi-PET imaging of in vivo fibrosis in inflammatory bowel disease patients

Published: 21-02-2023
Last updated: 03-06-2024

1. To evaluate the feasibility of 68Ga-FAPi PET/CT in detecting intestinal fibrosis in patients with IBD2.To optimize the acquisition and reconstruction methodology and identifying simplistic uptake measurements for FAPi PET/CT for detecting and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON53519

Source
ToetsingOnline

Brief title
PIMAFI

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, Inflammatory bowel disease, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fibrosis, Imaging, Inflammatory bowel disease

Outcome measures

Primary outcome

1. Visual and quantitative 68Ga-FAPi uptake measurements in the terminal ileum and colon on baseline PET/CT of stricturing Crohn*s disease patients compared to bowel reference values as derived in other Amsterdam UMC 68Ga-FAPi imaging studies in patients not suffering from IBD (when signed informed consent available).

2. Visual and quantitative 68Ga-FAPi uptake measurements in the terminal ileum and colon on baseline PET/CT of ulcerative colitis patients compared to bowel reference values as derived in other Amsterdam UMC 68Ga-FAPi imaging studies in patients not suffering from IBD (when signed informed consent available).

Secondary outcome

1. Visual and semi-quantitative evaluation of the pharmacokinetics (PK) of 68Ga-FAPi in patients with a) Crohn*s disease and b) ulcerative colitis compared to bowel uptake reference values as derived in other Amsterdam UMC 68Ga-FAPi imaging studies in patients not suffering from IBD (when signed informed consent is available).

2. To define optimal (single and/or dual) time point(s) post injection for imaging FAP activity in Crohn*s disease and ulcerative colitis.

3. Determine the minimal tracer injection dose required to have comparable disease detection performance on PET as to the full tracer injection dose PET.

Exploratory endpoint:

To determine to what extent 68Ga-FAPi bowel uptake in IBD patients corresponds

to conventional imaging modalities and FAP protein and transcriptome expression

levels.

Study description

Background summary

Intestinal fibrosis is a complication that is frequently seen in Inflammatory Bowel Disease (IBD) patients. At present, no anti-fibrotic treatments have been analysed in patients suffering from IBD. Of note, outcome measures to determine and quantify intestinal fibrosis in vivo are lacking, which hampers the development of potential anti-fibrotic molecules.
The 68Ga-fibroblast activation protein inhibitor (FAPI) PET-CT scan is a promising diagnostic tool for the visualisation of in vivo fibrosis and fibrogenesis in patients with active fibrosis due to chronic inflammation. This imaging modality targets Fibroblast Activation Protein alpha (FAPα) which has been reported to overexpressed in fibrosis. However, there is currently limited data of FAP imaging in chronic inflammatory diseases such as IBD and the potential it holds to be used for disease monitoring.

Study objective

1. To evaluate the feasibility of 68Ga-FAPi PET/CT in detecting intestinal fibrosis in patients with IBD
2.To optimize the acquisition and reconstruction methodology and identifying simplistic uptake measurements for FAPi PET/CT for detecting and measuring intestinal fibrosis.

Study design

Single-centre, pilot visibility imaging study

Study burden and risks

The burden of study participation is low. No evident health-related risks have been identified during prior studies with the 68Ga-FAPi PET/CT scanning. It is well tolerated but does require longer preparation compared to other conventional imaging modalities. The estimated total radiation burden per 68Ga-FAPi-PET/ldCT scan per patient will be up to 4.1 mSv .

The additional risk of this scan for patients is the intravenous access cannula for 68Ga-FAPi administration; which could give a local hematoma or run subcutaneously. The risks of all before mentioned complications are minimized by involving the department of Anesthesiology to insert these arterial cannulations. Patients will receive standard of care as determined by their attending physician. IUS will be performed at location AMC and is a well-tolerated and non-invasive diagnostic tool. Patients will also have to travel to the imaging centre to undergo a FAPi-scan at location VUMC. We expect that our study procedures will inflict limited additional burden to the subjects.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Group 1 - Adults >=18 years with confirmed diagnosis of Crohn*s disease AND one of the following: - Gastrointestinal complaints such as diarrhea, bloody and/ or lose stools and abdominal pain, or obstructive symptoms. - Increased CRP (>5 mg/L) and/or fecal calprotectin levels (>250 mg/kg) - Active disease confiremed by endoscopy (endoscopic SES-CD score >3) - Active disease confirmed by IUS or MRI (bowel wall thickening, signs of active disease) Group 2 - Adults >=18 years with confirmed diagnosis of ulcerative colitis AND one of the following: - Active disease confirmed by endoscopy (endoscopic Mayo score >= 2) or - Active disease confirmed by intestinal ultrasound (BWT > 3 mm in atleast one bowel segment and atleast one other pathological IUS parameter) - Increased CRP (>5 mg/L) and/or fecal calprotectin levels (>250 mg/kg)

Exclusion criteria

- Pregnancy
- Unable to provide informed consent
- IBD-related surgeries less than 5 years ago in medical history
- Colorectal cancer

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-08-2023
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[68Ga]FAPI-46
Generic name:	[68Ga]FAPI-46

Ethics review

Approved WMO Date:	21-02-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-05-2024
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
EudraCT	EUCTR2022-002751-19-NL
CCMO	NL82160.029.22