

Detecting local inflammation by 18F-FDG-WBC PET/CT as cause of primary delayed gastric emptying after pancreatoduodenectomy (PET-DGE study)

Published: 23-11-2009

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To investigate whether local inflammation in the area of the stomach and gastroenteric anastomosis is a cause of primary DGE.

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

Summary

ID

NL-OMON33302

Source

ToetsingOnline

Brief title

PET-DGE study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Hepatobiliary neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym

Pancreatic and periampullary carcinoma, pancreatic cancer

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 18F-FDG-labelled leukocytes, Delayed gastric emptying, Pancreatoduodenectomy, PET/CT scan

Outcome measures

Primary outcome

Inflammatory activity in the area of stomach and gastroenteric anastomosis, expressed as intestinal SUV-max.

Secondary outcome

Not applicable

Study description

Background summary

Delayed gastric emptying (DGE) is one of the most common complications after pancreatoduodenectomy (PD). Etiology of primary DGE is unknown. Local intra-abdominal inflammation may cause DGE. PET/CT using 18F-FDG-labelled white blood cells can detect such focal sites of inflammation.

Study objective

To investigate whether local inflammation in the area of the stomach and gastroenteric anastomosis is a cause of primary DGE.

Study design

Prospective cohort study; observational study with invasive measurements

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: No negative side effects of the PET/CT using

18F-FDG labelled white blood cells have been described. In this patient group, evidence supporting that local inflammation is a causative mechanism of primary DGE may offer treatment options

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Scheduled for explorative laparotomy with intention of pancreatoduodenectomy for pancreatic or periampullary disease

Age \geq 18 years

Willing and able to give written informed consent

Exclusion criteria

Peroperative findings of unresectability
Secondary DGE (DGE due to other intra-abdominal complications)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	32
Type:	Anticipated

Ethics review

Approved WMO	
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
CCMO	NL29061.018.09