Exocrine Pancreatic Insufficiency in Pancreatic Surgery (EPIPS): A prospective multicenter study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Exocrine pancreas conditions
Study type	Observational invasive

Summary

ID

NL-OMON38667

Source
ToetsingOnline

Brief title
EPIPS

Condition

- Exocrine pancreas conditions

Synonym
exocrine pancreatic insufficiency, malabsorption

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Abbott

Intervention

Keyword: exocrine pancreatic insufficiency, pancreatic cancer, pancreatoduodenectomy

Outcome measures

Primary outcome

The primary outcome parameters are the presence of EPI (FE1<200) and the percentage of patients that is under treated for EPI, i.e. patients who should receive treatment for EPI based on fecal elastase 1 test and patients who are treated for EPI but still experience symptoms reflecting EPI.

Secondary outcome

Secondary outcome parameters are symptoms of EPI (according to the CTC-AE score), the occurrence of vitamin A, D, E, and K deficiencies and a prolonged INR, endocrine pancreatic insufficiency (HbA1c > 42 mmol/l and/or use of oral antidiabetics or insulin), QOL (EQ-5D, QLQ-C30, and QLQ-PAN26), and the course of EPI over time.

Study description

Background summary

Exocrine pancreatic insufficiency (EPI) is caused by loss of pancreatic parenchyma (e.g. after surgical resection) or obstruction of the pancreatic duct (e.g. tumour) and leads to loss of quality of life (QOL) and potential worsened long term outcome. Furthermore, EPI is easily treatable with pancreatic enzyme replacement therapy.
Following a pancreatoduodenectomy (PD) EPI is observed in 33-90% of patients. However, these data are based on small retrospective studies. To date, there are no multicenter prospective studies that have investigated the (course of) exocrine pancreatic function after a PD, neither on the short-term, nor on the long-term.
We hypothesize that EPI is frequently underdiagnosed which may be related to the variable signs and symptoms associated with EPI. This may lead to under

treatment, high prevalence of vitamin deficiencies, osteopenia/osteoporosis and poor QOL.

Study objective

To analyze the incidence and course of EPI, before and after a PD for a (suspected) pancreatic or peri-ampullary (pre-)malignancy. Furthermore, the correlation between the presence of EPI and symptoms will be evaluated. In addition, the incidence of fat-soluble vitamin deficiencies and osteopenia/ -porosis will be evaluated. Finally, endocrine pancreatic function and QOL will be analysed.

Study design

In this prospective multicenter observational cohort study, the presence of EPI will be evaluated in two groups; the first group (cohort A) will be followed before and during the first 18 months after PD, to evaluate short-term EPI. The second cohort (cohort B) will also be followed for 18 months, but consists of patients who have already survived at least 2 years after PD, to evaluate the long-term EPI course.

Study burden and risks

The burden associated with participation consists of the drawing of blood samples and the collection of a stool sample. In addition, subjects will be asked to complete a questionnaire. Patients in cohort B will also have a DEXA scan. There are no risks associated with participation.

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

Cohort A
• Patients who will undergo a pancreatoduodenectomy for a suspected or confirmed pancreatic or peri-ampullary (pre-) malignancy.
• Informed consent;Cohort B
• Patients who underwent a PD for suspected or confirmed pancreatic or peri-ampullary (pre-) malignancy at least two years previously.
• Informed consent

Exclusion criteria

• Patients younger than 18 years
• Other causes of fat malabsorption (inflammatory bowel disease, cystic fibrosis, celiac disease, major gastrointestinal surgery other than PD).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-06-2014
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	04-02-2014
Application type:	First submission
Review commission:	METC NedMec

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	NL43502.041.13