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

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To analyze the incidence and course of EPI, before and after a PD for a suspected pancreatic or peri-ampullary malignancy. Furthermore, the effect of pancreatic enzyme supplementation on symptoms of EPI and the correlation of symptoms and abnormal...

Ethical review	Not approved
Status	Will not start
Health condition type	Exocrine pancreas conditions
Study type	Observational invasive

Summary

ID

NL-OMON37197

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), Quality-of-life (RAND-36, QLQ-C30, and QLQ-PAN26), and the effect of pancreatic enzyme supplementation on symptoms of EPI.

Study description

Background summary

The pancreas has both an endocrine and exocrine function. Exocrine pancreatic insufficiency (EPI) and vitamin deficiency after pancreatoduodenectomy is described in 33-90% of cases. These data are based on personal experiences and short-term results from retrospective studies. To date, there are no prospective studies that describe exocrine pancreatic insufficiency on both short-and long-term after pancreatoduodenectomy.

Study objective

To analyze the incidence and course of EPI, before and after a PD for a suspected pancreatic or peri-ampullary malignancy. Furthermore, the effect of pancreatic enzyme supplementation on symptoms of EPI and the correlation of

symptoms and abnormal fecal elastase 1 test will be evaluated. In addition, the prevalence of fat-soluble vitamin deficiencies and osteoporosis will be evaluated. Finally, the endocrine function and quality-of-life 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 during the first 18 months after surgery, to evaluate short-term EPI. The second cohort (group B) will be followed for the same period, and consists of patients who have already survived at least 2 years after surgery, to evaluate the long-term EPI course.

Study burden and risks

A potential benefit of participation is early diagnosis and adequate treatment of (subclinical) EPI. Even without personal benefit for participating patients, this study is of great importance to the treatment of EPI and the related benefits in nutrional status and quality of life.
All study related investigations will take place during routine follow-up moments (including the inclusion visit there will be 5 appointments in group A and 4 in group B). Therefore, patients will not suffer the burden of additional hospital visits. Each visit will include a short questionnaire (5-10 minutes) and the examination of a stool sample, which patients can obtain at the privacy of their own home. We acknowledge a small burden, but consider these tests without risk. In addition blood samples will be drawn to assess vitamin A, D, E and K status and blood glucose levels (total 14mL blood). This may be perceived as a small burden, but has negligible risks.

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

Group A
* Patients who will undergo a pancreatoduodenectomy for a suspected pancreatic or peri-ampullary malignancy ;Group B
* Patients who underwent pancreatoduodenectomy for suspected pancreatic or peri-ampullary malignancy at least two years previously

Exclusion criteria

Patients younger than 18 years

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	120
Type:	Anticipated

Ethics review

Not approved

Date:	27-11-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL41202.041.12