A prospective, descriptive cohort study evaluating the prevalence and incidence of exocrine pancreatic insufficiency in patients with pancreatic cancer.

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Primary Objective:- To determine the incidence of EPI in pancreatic cancer.Secondary Objectives are: 1. To identify the predictive factors for the development of EPI in pancreatic cancer.2. To evaluate the occurrence of nutritional deficiencies in…

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

Summary

ID

NL-OMON35011

Source
ToetsingOnline

Brief title
Prevalence, incidence of EPI in pancreaticcancer

Condition

- Exocrine pancreas conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreatic exocrine insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Pancreatic cancer, Pancreatic exocrine insufficiency

Outcome measures

Primary outcome

The incidence of EPI in pancreatic cancer: EPI is defined as a FET < 0.200 mg/g

during follow-up. .

Secondary outcome

What is the predictive value of different disease characteristics during the

development of EPI?

o tumour localisation (pancreas, distal cholangiocarcinoma and papillary

tumours)

o tumour size

o metastases (metastases in solid organs: liver and lungs and/or lymph noduli

>1 cm in size)

o vascular tumour infiltration

o tumour resectability

o different operative techniques

o steatorrhea related symptoms (stool frequency and consistency, stomach aches

and/or flatulence, sticky stool)

o weight loss (BMI)

o presence of jaundice

o presence of diabetes mellitus during disease process

o the presence of nutritional deficiencies

o subjective pain-score (1-10)

o doses of pain medication

Study description

Background summary

Pancreatic cancer is the fourth leading cause of cancer-related death in the United States and is the second cause next to colorectal cancer of digestive cancer-related death. The only potentially curative treatment is surgical resection, but due to the late presentation of this disease, only 10-20% of the patients are candidates for a pancreatectomy. The prognosis of pancreatic cancer, even in those with a potentially resectable disease, is poor. The five-year survival following a pancreatico¬duodenectomy is approximately 25-30% for node negative tumors and 10% for node positive tumors. Recent data suggests that survival may be improving over time, possibly related to improved forms of treatment including palliative chemotherapy and (neo)adjuvant chemoradiotherapy next to surgical resection.
Weight loss in cancer in general is amongst others caused by primary tumour effects which instigate metabolic abnormalities such as an increased glucose production, increased lipolysis, increased body protein breakdown and depletion of body fat stores. Due to secondary tumour effects (e.g. side effects of treatment, mechanical and intestinal obstruction) above mentioned effects can be augmented. In case of pancreatic cancer, secondary tumour effects such as pancreatic duct obstruction, replacement of parenchyma by neoplasm, gland fibrosis and atrophy can cause exocrine pancreatic insufficiency.
Patients who develop exocrine pancreatic insufficiency due to pancreatic cancer suffer from nutritional deficiencies resulting from the malabsorption from fat, protein and carbohydrates. Development of exocrine pancreatic insufficiency (early) in the course of disease is frequently overlooked, because the focus of attention of both patient and physician is directed at chemo(radio)therapy and its potential side effects. Loss of appetite caused by steatorrhoea associated complaints (bloating, abdominal cramps, foul smelling, grey, frothy stools) are frequently falsely attributed to the effects of the primary tumour.
The actual prevalence and incidence of exocrine pancreatic insufficiency in pancreatic cancer is a relatively unknown fact.
The aim of this study is to determine the timely incidence and prevalence of

exocrine pancreatic insufficiency in pancreatic cancer by means of a repeated elastase-1 test.

Study objective

Primary Objective:
- To determine the incidence of EPI in pancreatic cancer.
Secondary Objectives are:
1. To identify the predictive factors for the development of EPI in pancreatic cancer.
2. To evaluate the occurrence of nutritional deficiencies in pancreatic cancer.
3. To assess the efficacy of pain medication in pancreatic cancer.

Study design

This is a prospective, descriptive observational cohort study. Patients who are recently diagnosed with pancreatic cancer will be followed during their disease course. EPI will be evaluated by means of a monthly repeated FET.
Pancreatic enzyme replacement treatment (PERT) is started if FET < 0.1 mg/g.
In addition, each month patients will complete a short questionnaire to assess the presence of signs and symptoms of EPI.
Every three months blood will be drawn to analyse the nutritional status.
The follow up in inoperable patients will continue as long as the condition of the patient allows it. The follow up in operative patients will continue until 6 months after the operation.

Study burden and risks

There are no risks foreseen in joining this study.
When a exocrine pancreatic insufficiency is proven in a patient, he or she will receive pancreatic enzyme suppletion treatment during the rest of their disease process.

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

Patients who are considered for this trial:
- Age >= 18 years.
- Malignant tumours of the pancreas, distal cholangiocarcinoma and papillary tumours proven by means of cytology/histology and/or radiology.
- are capable and willing to follow instructions given by the physician.

Exclusion criteria

The following are considered as exclusion criteria:
- Subjects who are unwilling or unable to understand and participate in the study and sign the informed consent.
- Pre-existent EPI
- Pre-existent malabsorption (short bowel disease, IBD, other)
- Any known gastro-intestinal disease or major gastrointestinal surgery that could potentially affect the intestinal absorption or metabolism of fat
- Total pancreatectomy
- Gastroparesis
- Pregnancy/lactation
- Patients who are suspected not to be reliable in participating in this study, based on the physicians experience.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	25-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-01-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL30337.078.09