PReoperative Optimisation of Modifiable rIsk factorS in surgEry of the Pancreas: the implementation of best practice before pancreatic resection

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To investigate whether implementation of a best practice program for preoperative optimisation of patients with a focus on screening, assessment, and intervention of 8 potentially (partly) modifiable risk factors (low (aerobic) fitness level,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Benign neoplasms gastrointestinal
Study type	Interventional

Summary

ID

NL-OMON56511

Source
ToetsingOnline

Brief title
PROMISE-P

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms malignant and unspecified
- Lifestyle issues

Synonym
disease of the pancreas, Pancreatic tumour

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Rising Tide Foundation for Clinical Cancer Research

Intervention

Keyword: Pancreas, Prehabilitation, Preoperative optimisation, Surgery

Outcome measures

Primary outcome

The primary outcome is time to functional recovery after surgery, which is achieved when all of the following five criteria are met: a) restored level of mobility to the level of independence (or to the preoperative level in case mobility was preoperatively already impaired), b) sufficient pain control with oral medication alone, c) ability to maintain at least 50% daily required protein and energy intake, d) no intravenous fluid administration, and e) no clinical signs of infection (CRP < 150 mg/L and temperature < 38.5 degrees Celsius).

Secondary outcome

The most relevant secondary outcomes are the Comprehensive Complication Index (CCI), complications graded by Clavien-Dindo classification, length of hospital stay, readmission rate, quality of life and (cost) effectiveness.

Study description

Background summary

For pancreatic tumours, pancreatic resection is the cornerstone of curative treatment. It is a major abdominal operation with up to 50% postoperative

morbidity. Patients with pancreatic and periampullary (pre)malignant tumours (and sometimes pancreatitis) often suffer from severe weight loss and loss of physical condition at the time of diagnosis, also known as (cancer) cachexia.

In studies, audits and the daily clinical practice, focus is on the treatment itself, its complications and (long-term) outcome after treatment. Little attention is given to the physical and mental condition of the patient at the time of the diagnosis, before the treatment commences. However, e.g. reduced preoperative aerobic fitness and preoperative anxiety have been associated with worse postoperative outcome such as a higher chance for a postoperative complication. Adequate preoperative screening to identify patient-related modifiable risk factors associated with adverse outcomes and subsequently influencing these risk factors in a multimodal, patient centred prehabilitation program appears a promising intervention to improve outcomes of patients undergoing pancreatic resection. Therefore, the hypothesis is that if the patient's condition is optimised before major pancreatic surgery, the risk for or impact of complications can be reduced resulting in an accelerated time to recovery with an improved quality of life. Although promising, unfortunately, strong evidence to support the contribution of prehabilitation to optimize the functional outcome after surgery is still lacking.

Study objective

To investigate whether implementation of a best practice program for preoperative optimisation of patients with a focus on screening, assessment, and intervention of 8 potentially (partly) modifiable risk factors (low (aerobic) fitness level, malnutrition, low psychological resilience, comorbidities (iron deficiency (anaemia), impaired glucose control and frailty), and intoxications (alcohol and smoking behaviour)) will improve the time to functional recovery compared to current practice.

Study design

A nationwide stepped-wedge cluster randomized superiority trial. In this design all participating centres will cross over from current practice to the best practice program, in a randomised order. At the end of the trial, all centres will have implemented the best practice program. The best practice program is seen as standard care. In the current study, health related outcomes before and after introduction of the program will be compared.

Intervention

Preoperative screening of all patients scheduled for pancreatic resection on (aerobic) fitness level, malnutrition risk, psychological resilience, haemoglobin, iron and HbA1c concentration, frailty, and alcohol and smoking behaviour. All patients are provided with a patient-tailored, multimodal

prehabilitation program, in which these potentially (partly) modifiable factors are preoperatively addressed. This is considered the best practice care.

Study burden and risks

Prehabilitation in this study is considered standard care in the Netherlands for pancreatic surgery. Various prehabilitation programs have been proven save in different patient groups, like patients with colorectal cancer. Therefore, the risks associated with this program are very low. All of the 8 preoperative interventions are safe and already provided as standard care in some hospitals in the Netherlands. It is important to standardize the preoperative interventions in all hospitals to assess its effectiveness. The preoperative program and additional questionnaire can impose a burden to the patient in terms of time investment. Patients could benefit from the best practice preoperative program, since our hypothesis is that patients have a shorter time to functional recovery.

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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 scheduled to undergo pancreatic resection in one of the 13 participating DPCG centers in the Netherlands (including for (pre)malignant or benign lesions and chronic pancreatitis) or the intention to undergo pancreatic resection after neoadjuvant treatment (for malignant tumours)
- Understanding of and being able to read the Dutch language

Exclusion criteria

- Age < 18 years
- Being legally incapable
- Undergoing an acute pancreatic resection (resection scheduled within two weeks)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-09-2024
Enrollment:	2575
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	29-01-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-08-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-02-2025
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT05851534

Register
CCMO

ID
NL85426.068.23