Laparoscopic versus open distal pancreatectomy for symptomatic benign, premalignant and malignant disease

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To determine whether time to functional recovery is shorter after LDP than after ODP for symptomatic benign, premalignant and malignant disease of the distal pancreas in an enhanced recovery setting.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45123

Source
ToetsingOnline

Brief title
LEOPARD trial

Condition

- Other condition
- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
cancer, tumor

Health condition

pancreasaandoeningen/pancreastumoren

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Bedrijf,Johnson & Johnson Medical B.V.

Intervention

Keyword: distal pancreatectomy, laparoscopy, pancreatic cancer, pancreatic cyst, pancreatic surgery

Outcome measures

Primary outcome

Primary outcome is the time (days) to functional recovery, defined as all of the following: independently mobile at the preoperative level, sufficient pain control with oral medication only, ability to maintain sufficient (> 50%) daily required caloric intake, no intravenous fluid administration and no signs of infection.

Secondary outcome

Main secondary outcome is the occurrence of major complications (i.e. Clavien-Dindo score of III or higher). Other secondary outcomes are I)intraoperative parameters such as splenectomy, conversion, operating time, blood loss and transfusion, II)postoperative outcomes such as complications, intensive care admission, length of hospital stay and readmission and III)pathology outcomes such as resection margin status and number of lymph nodes resected.

Study description

Background summary

Observational cohort studies suggest that laparoscopic distal pancreatectomy (LDP) as compared to open distal pancreatectomy (ODP) is associated with better outcomes, such as less intraoperative blood loss and reduced morbidity and length of hospital stay, without increased costs. However, selection bias has substantially influenced these findings and case-matched studies failed to demonstrate superiority of LDP. A randomized trial is therefore needed.

Study objective

To determine whether time to functional recovery is shorter after LDP than after ODP for symptomatic benign, premalignant and malignant disease of the distal pancreas in an enhanced recovery setting.

Study design

A randomized controlled, parallel-group, pragmatic, blinded, superiority multicenter trial in 17 centers of the Dutch Pancreatic Cancer Group. The study protocol is designed according to the SPIRIT 2013 guidelines.

Intervention

Intervention: Laparoscopic distal pancreatectomy (+ / - splenectomy).
Control: Open distal pancreatectomy (+ / - splenectomy).

Study burden and risks

Recent meta-analyses of cohort studies suggest that LDP is superior to ODP concerning blood loss, complications and hospital stay but these benefits could not be confirmed by case-matched studies. Subjects will not undergo additional investigations and interventions due to participation in the LEOPARD study and therefore risks to subjects involved in this trial are similar to every other patient undergoing distal pancreatectomy in routine clinical practice.
Potential benefits for subjects in the investigational treatment arm could be less intraoperative blood loss, fewer major complications, expedited functional recovery, a shorter hospital stay and better cosmesis.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age equal or above 18 years;
* Indication for elective distal pancreatectomy (+ / - splenectomy) because of proven or suspected symptomatic benign, premalignant or malignant disease of the distal pancreas (as defined in section 4.4);
* Tumor meeting the Yonsei criteria33:
* Fit to undergo distal pancreatectomy according to the surgeon and anaesthetist.

Exclusion criteria

* Tumor or cyst larger than 8 cm;
* Distal pancreatectomy is not the sole procedure, so when a surgical intervention (resection / ablation) of other organs besides the distal pancreas or spleen is performed (minor procedures, such as cholecystectomy, are allowed);
* Chronic pancreatitis (according to the M-ANNHEIM criteria, see Appendix 2 for detailed definition);

* Previous radiotherapy for pancreatic cancer;
* Pregnancy;
* Participation in another study with interference of study outcomes.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-04-2015
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-05-2015
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-05-2017
Application type:	Amendment
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

ID: 26260
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL52031.018.15
OMON	NL-OMON26260