Minimally invasive versus open pancreatoduodenectomy

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The objective of the LEOPARD-2 trial is to assess the safety of MIPD versus OPD and after that to assess the time to functional recovery of MIPD versus OPD for symptomatic benign, premalignant or malignant peri-ampullary disease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44749

Source
ToetsingOnline

Brief title
LEOPARD-2 trial

Condition

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

Synonym
cancer, tumor

Health condition

peri-ampullaire aandoeningen/tumoren/cysten

Research involving
Human

Sponsors and support

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

Intervention

Keyword: HPB-surgery, Laparoscopy, Pancreatoduodenectomy, Peri-ampullary cancer

Outcome measures

Primary outcome

Phase 2:

- IL-6 serum levels

Phase 3:

- Time to functional recovery, defined as: independently mobile (or as mobile as preoperatively), adequate pain control with only oral analgesia, the ability to maintain at least 50% of daily required caloric intake, no intravenous fluid administration, no signs of active infection.

Secondary outcome

- Clavien-Dindo III or higher complications
- Individual complications
- Mortality
- Quality of life
- Costs
- Other operative outcomes
- Other postoperative outcomes

Study description

Background summary

Observational studies suggested that LPD versus OPD is associated with improved outcomes, such as less operative blood loss, lower postoperative morbidity and shorter length of hospital stay, without increasing costs. However, these outcomes are obviously influenced by selection bias and case-matched studies failed to show clear superior outcomes. A randomized controlled trial is therefore indicated. First, the safety of LPD versus OPD has to be determined, which is followed by assessing the potential advantages of LPD over OPD in a large randomized controlled trial in high-volume centers.

Study objective

The objective of the LEOPARD-2 trial is to assess the safety of MIPD versus OPD and after that to assess the time to functional recovery of MIPD versus OPD for symptomatic benign, premalignant or malignant peri-ampullary disease.

Study design

A randomized controlled, parallel-group, pragmatic, patient-blinded, phase 2/4, multicenter superiority study in high-volume centers of the Dutch Pancreatic Cancer Group. The study protocol is designed according to the SPIRIT 2013 guidelines.

Intervention

Intervention: Minimally invasive pancreatoduodenectomy
Control: Open pancreatoduodenectomy

Study burden and risks

Recent meta-analyses of cohort studies suggested that LPD is superior to OPD concerning operative blood loss, complications and length of hospital stay, but these advantages were not seen in case-matched studies. Furthermore, LPD appeared to be safe in the prospective series from the Dutch Pancreatic Cancer Group, with comparable morbidity and mortality for LPD and OPD. The risks in the LEOPARD-2 trial are comparable to the risks of every other patient undergoing pancreatoduodenectomy in routine clinical practice. Potential benefits for subjects in the investigational arm could be less operative blood loss, fewer major complications, expedited functional recovery, a shorter hospital stay and better cosmesis.

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

• Age equal or above 18 years
• Indication for elective pancreatoduodenectomy because of a malignant, pre-malignant or symptomatic benign disease located in the pancreatic head, distal bile duct, duodenum or ampulla of Vater
• The procedure can be performed both laparoscopically and open according to the local surgeon
• Fit to undergo pancreatoduodenectomy according to the surgeon and anaesthetist

Exclusion criteria

• A second cancer requiring resection during the same procedure

• Administration of neo-adjuvant radiotherapy
• Vascular involvement (portal vein, superior mesenteric vein, superior mesenteric artery or hepatic artery)
• Pregnancy
• Body mass index >35 kg/m2
• 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:	Recruitment stopped
Start date (anticipated):	02-03-2016
Enrollment:	136
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	03-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2018
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: 22778
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54453.018.15

Register	ID
OMON	NL-OMON22778