Minimally invasive versus open pancreatoduodenectomy

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22778

Source
NTR

Brief title
LEOPARD-2 phase 2

Health condition

Pancreatic and peri-ampullary disease

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Safety parameters and IL-6 serum levels

Secondary outcome

Other operative and postoperative outcomes

Study description

Background summary

Inclusion of phase 2 is completed on 20-12-2016, the data safety monitoring board allowed the start of phase 3 on 29-01-2017. Primary outcome of phase 3 is time to functional recovery. Patients included in phase 2 are also included in phase 3. Inclusion and exclusion criteria for phase 2 and phase 3 are equal. Target number of patients is 136 (94 additional patients) and planned closingdate is 29-01-2018.

Study objective

Minimally invasive pancreatoduodenectomy is as safe as open pancreatoduodenectomy

Study design

- Baseline

- Operation

- 2 weeks postoperatively

- 1 month postoperatively

- 3 months postoperatively

Intervention

- Minimally invasive pancreatoduodenectomy

- Open pancreatoduodenectomy

Contacts

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Eligibility criteria

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 minimally invasive 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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	02-03-2016
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-03-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44749
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5556
NTR-old	NTR5689
CCMO	NL54453.018.15
OMON	NL-OMON44749

Study results