Laparoscopic versus robot-assisted left-sided pancreatectomy for benign and pre-malignant lesions (DIPLOMA-3): an international multicenter patient-blinded randomized controlled trial

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To compare L-MILP with R-MILP for benign and pre-malignant lesions of the pancreas in high-volume centers, regarding:1. Peri- and postoperative outcomes in terms of COMPOS-panc left score, for non-inferiority2. Total hospital-related costs, for…

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

Summary

ID

NL-OMON57427

Source
ToetsingOnline

Brief title
DIPLOMA-3 trial

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal therapeutic procedures

Synonym
Benign and premalignant lesions

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Distal pancreatectomy, Left-sided pancreatectomy, Minimally invasive surgery, Pancreatic resection

Outcome measures

Primary outcome

The primary outcome is the COMPOS-panc left score, which combines perioperative and postoperative outcomes into a single, severity-weighted outcome. This score includes the following parameters, measured at 90-days postoperative: unplanned blood transfusion, emergency conversion to open surgery, postoperative pancreatic fistula (POPF), postpancreatectomy hemorrhage (PPH), other complications requiring intervention, multi-organ failure, mortality, length of hospital stay and readmission requiring intervention.

Secondary outcome

The most relevant secondary endpoint is total hospital-related costs and includes analyses of the direct cost of the operation, the direct cost of the post-operative hospital period and the total cost of the follow-up period, including readmission, outpatient visits, emergency room visits and reintervention up to 90-days postoperative.

Other secondary endpoints are intra-operative outcomes (e.g. type of left-pancreatectomy (LP), blood loss, operative time, conversion, method of pancreatic transection, spleen-preservation rate, Kimura/Warshaw technique,

vascular resection, extended resection), postoperative pain, post-operative

morbidity (e.g. Clavien-Dindo scores, surgical site infection (SSI),

non-surgical complications, pancreatic surgery specific complications according

to ISGPS definitions), ideal outcome, health-care resource utilization (e.g.

ICU stay), surgeon*s mental and physical strain and quality of life.

Study description

Background summary

Minimally invasive left-sided pancreatectomy (MILP) is currently the recommended approach for treatment of benign and low-grade malignant lesions of the pancreas, showing favorable outcomes over open left-sided pancreatectomy (OLP). Robot-assisted MILP (R-MILP) is slowly gaining popularity because of potential intraoperative technical advantages, such as 3D visualization and improved dexterity, possibly contributing to lower postoperative morbidity. However, multiple studies have shown an increase in costs when R-MILP is compared with laparoscopic MILP (L-MILP). Moreover, L-MILP and R-MILP have shown comparable morbidity and mortality in multiple retrospective studies, raising the question if the use of R-MILP over L-MILP is justifiable considering these increasing costs. Yet, no randomized controlled trials (RCTs) have compared clinical outcomes after L-MILP and R-MILP. Furthermore, such studies could determine whether L-MILP is more cost-effective then R-MILP.

Study objective

To compare L-MILP with R-MILP for benign and pre-malignant lesions of the pancreas in high-volume centers, regarding:
1. Peri- and postoperative outcomes in terms of COMPOS-panc left score, for non-inferiority
2. Total hospital-related costs, for superiority (for L-MILP)
3. Spleen-preservation rate, for superiority (for R-MILP)

Study design

An international multicenter patient-blinded randomized controlled trial in high-volume centers with a minimum experience of 85 minimally invasive pancreatic resections (MIPR) and surgeons with a personal experience of at least 30 MIPR, combining both left-sided pancreatectomy and pancreatoduodenectomy (either laparoscopic or robot-assisted, depending on the

procedure they will be performing during the trial) can participate. Centers can only participate if both R-MILP and L-MILP can be performed, to ensure randomization within a center is possible. A blinded adjudication committee will assess all endpoints. The protocol is designed according to the SPIRIT guidelines.

Intervention

Minimally invasive, laparoscopic or robot-assisted, left-sided pancreatectomy

Study burden and risks

No additional risks are associated with participation in the DIPLOMA-3 trial. Both laparoscopic and robotic left-sided pancreatectomy are currently part of standard practice in high-volume experienced HPB centers. Both procedures have shown similar peri- and postoperative outcomes in retrospective studies. The only additional patient burden during the trial is the completion of quality of life questionnaires at multiple timepoints pre- and postoperative.

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 at least 18 years;
- Indication for elective left-sided pancreatectomy (either only tail, body-tail, neck-body-tail, extended neck-body-tail), either spleen-preserving or non-preserving (because of proven or suspected left-sided benign or premalignant disease);
- Both robot-assisted and laparoscopic left-sided pancreatectomy are technically feasible for resection, according to the local treatment team;
- Fit to undergo left-sided pancreatectomy according to the surgeon and anaesthesiologist;
- Written informed consent.

Exclusion criteria

- Suspected pancreatic ductal adenocarcinoma;
- Tumor or cyst larger than 8 cm;
- Required resection or ablation of organs other than pancreas and spleen;
- Tumor involvement or abutment of major vessels (celiac trunk, mesenteric artery or vena cava);
- Pregnancy;
- Body mass index >40 kg/m2;
- Participation in another study with interference of study outcomes.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2025
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-04-2025
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL88413.018.24