

Robot-assisted versus open extended lateral pancreaticojejunostomy for the treatment of symptomatic chronic pancreatitis (PANACOTTA): a multicenter patient- and assessor-blinded randomized trial

Published: 09-01-2025

Last updated: 18-01-2025

To assess the post-operative quality of recovery after robot-assisted as compared to open extended lateral pancreaticojejunostomy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON57233

Source

ToetsingOnline

Brief title

PANACOTTA

Condition

- Gastrointestinal therapeutic procedures

Synonym

Chronic pancreatitis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum

Source(s) of monetary or material Support: niet van toepassing, Viatrix

Intervention

Keyword: Chronic pancreatitis, Extended lateral pancreaticojejunostomy

Outcome measures

Primary outcome

Primary: Quality of recovery as measured by the QoR-15.

Secondary outcome

Secondary: blood loss, total operative time, complications (surgical site infection, delayed gastric emptying, postoperative pancreatic fistula, postpancreatectomy haemorrhage), cumulative opioid consumption, all-cause mortality, time to functional recovery, area under the curve of QoR-15 until conditions of time to functional recovery are met, hospital stay, readmission(s) for any indication, quality of life, costs, endoscopic interventions, surgical interventions, new-onset endocrine pancreatic insufficiency, new-onset exocrine pancreatic insufficiency, pain (Izbicki pain score, COMPAT, NRS), disease progression.

Study description

Background summary

Surgery is the treatment of choice for patients with painful chronic pancreatitis and a dilated main pancreatic duct and is typically performed via laparotomy. However, pain control in the first days after surgery may be problematic in these patients. For this reason, a minimally invasive robot-assisted extended lateral pancreaticojejunostomy may improve

postoperative pain control and lead to faster post-operative recovery. However, randomized trials validating these benefits have not been performed.

Study objective

To assess the post-operative quality of recovery after robot-assisted as compared to open extended lateral pancreaticojejunostomy.

Study design

Multicenter randomized controlled patient- and assessor blinded trial.

Intervention

Robot-assisted extended lateral pancreaticojejunostomy

Study burden and risks

Participating patients are burdened with questionnaires during follow-up.

Contacts

Public

Selecteer

De Boelelaan 1117
Amsterdam 1081 HV
NL

Scientific

Selecteer

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. At least 18 years old
2. Indication for extended lateral pancreaticojejunostomy as agreed during multidisciplinary team meeting based on symptomatic CP (i.e. morphine dependent pain or recurrent acute pancreatitis)
3. Dilated pancreatic duct of ≥ 5 mm, without enlarged pancreatic head < 40 mm
4. Confirmed CP, according to the M-ANNHEIM diagnostic

Criteria 22

- Typical clinical history of chronic pancreatitis (i.e. recurrent pancreatitis or abdominal pain), and:

- One or more of the following additional criteria

for the diagnosis of CP:

- o Pancreatic calcifications on CT or MRI imaging.
- o Moderate or marked ductal lesions (according to the Cambridge classification) on endoscopic retrograde cholangiopancreatography (ERCP) or magnetic resonance cholangiopancreatography (MRCP) imaging.
- o Marked and persistent exocrine insufficiency (defined as: a. pancreatic steatorrhea clearly relieved by enzyme supplementation, and/or b. fecal elastase levels of ≤ 200 micro gram/gram).

5. Eligible for both a robot-assisted and open approach
6. Obtained written informed consent

Exclusion criteria

1. Suspected or confirmed current pancreatic malignancy
2. Known allergy / contraindication for epidural anesthesia
3. ASA classification ≥ 4
4. Other painful conditions aside from chronic pancreatitis, making it unable to differentiate between pain related to chronic pancreatitis and pain stemming from other sources
5. Stones and strictures exclusively located in the tail of the pancreas (i.e. to the left of the vertebra) with relatively normal pancreatic head and corpus
6. Prior pancreatic surgery
7. Pregnancy

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	06-01-2025
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO	
Date:	09-01-2025
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

CCMO

ID

NL87297.018.24