Antecolic versus retrocolic route of the gastroenteric anastomosis after pancreatoduodenectomy: ARCO-trial

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Primary objective:To determine the relationship of route of gastroenteric anastomosis after PD and postoperative incidence of DGE.Secondary objectives:To determine the relationship of route of gastroenteric anastomosis after PD and gastric emptying...

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON35553

Source
ToetsingOnline

Brief title
ARCO-trial

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Hepatobiliary neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
cancer of the pancreas, Pancreatic and periampullary carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Delayed gastric emptying, Gatroenteric anastomosis, Pancreas, Pancreatoduodenectomy

Outcome measures

Primary outcome

Postoperative incidence of DGE according to the definition by the International

Group of Pancreatic Surgery (ISGPS).

Secondary outcome

-Gastric emptying measured by scintigraphy (AMC patients only)

-Quality of life

-Postoperative complications

-Length of stay

-Costs

Study description

Background summary

Though mortality has dropped below 5%, morbidity of pancreatic surgery remains high (30%-50%). One of the most common complications after pancreatoduodenectomy (PD) is delayed gastric emptying (DGE). In recent literature, incidences vary from 19% to 57%. DGE leads to longer hospital stay, higher costs and decreases quality of life. This pertains especially to DGE grade B ("moderate") and C ("severe") according to the recently published definition by the International Study Group of Pancreatic Surgery (ISGPS).
The causative mechanisms of DGE are unknown. Some retrospective studies suggest a role for the route of gastroenteric anastomosis: antecolic or retrocolic gastrojejunostomy/duodenojejunostomy. A recent randomized trial by Tani et al. from Japan showed a tenfold difference in postoperative DGE incidence, in favour of the antecolic route (5% versus 50%). Small patient numbers and unclear definitions make it difficult to understand this enormous difference. A

new methodologically sound randomized trial seems required to compare the antecolic and retrocolic route.

Hypothesis: an antecolic route of gastroenteric anastomosis after pancreatoduodenectomy leads to lower postoperative DGE incidence than a retrocolic route.

Study objective

Primary objective:
To determine the relationship of route of gastroenteric anastomosis after PD and postoperative incidence of DGE.

Secondary objectives:
To determine the relationship of route of gastroenteric anastomosis after PD and gastric emptying (measured by scintigraphy), quality of life, postoperative complications, length of stay and costs.

Study design

Randomized controlled trial with blinding for treatment allocation of patient and medical personnel except surgeon.

Intervention

Antecolic route.
Control: retrocolic route.

Study burden and risks

There are no risks involved in study participation. Intervention and control methods are both safe and commonly accepted methods of gastroenteric reconstruction. Except a possible difference in postoperative incidence of DGE, no differences in complications have been described between antecolic and retrocolic reconstruction.
A possible disadvantage is that the surgeon will use another method of reconstruction than usual.
Gastric emptying scintigraphy is a non-invasive investigation with low radiation load.

Contacts

Public
Academisch Medisch Centrum

Postbus 22660
1100 DD Amsterdam
NL
Scientific
Academisch Medisch Centrum

Postbus 22660
1100 DD Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Planned explorative laparotomy for pancreatic or periampullary tumour, with resection if possible (pancreatoduodenectomy)
Age >18yrs
Able and prepared to give written informed consent

Exclusion criteria

Peroperative findings of unresectability

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	250
Type:	Anticipated

Ethics review

Approved WMO

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	NL25390.018.09