Antecolic versus Retrocolic Route of the Gastroenteric Anastomosis after Pancreatoduodenectomy: ARCO-trial.

No registrations found.

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

Summary

ID

NL-OMON26450

Source
Nationaal Trial Register

Brief title
ARCO-trial

Health condition

Pancreatic and periampullary tumors
Pancreatoduodenectomy
In Dutch:
Pancreas- en periampullaire tumoren
Pancreatoduodenectomie

Sponsors and support

Primary sponsor: AMC Medical Research B.V.
Source(s) of monetary or material Support: AMC Medical Research B.V.

Intervention

Outcome measures

Primary outcome

Postoperative incidence of delayed gastric emptying.

Secondary outcome

1. Gastric emptying rate assessed by scintigraphy (subset of patients);

2. Postoperative complications;

3. Length of stay;

4. Quality of life;

5. Costs.

Study description

Background summary

ARCO-trial – Antecolic versus RetroCOlic route of the gastroenteric anastomosis after pancreatoduodenectomy – summary.

Background:

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.

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.

Study population:

Patients of >18 years old with suspicion of pancreatic or periampullary tumor, woh will undergo explorative laparotomy with resection (pancreatoduodenectomy) if possible.

Intervention:

Antecolic route.
Control: retrocolic route.

Primary outcome parameter:

Postoperative incidence of DGE according to the definition by the International Group of Pancreatic Surgery (ISGPS).

Secondary outcome parameters:

1. Gastric emptying measured by scintigraphy (AMC patients only);

2. Quality of life;

3. Postoperative complications;

4. Length of stay;

5. Costs.

Study objective

An antecolic route of the gastroenteric anastomosis in pancreatoduodenectomy may lead to a lower postoperative incidence of delayed gastric emptying than a retrocolic route, thus reducing length of hospital stay, lowering medical costs and improving quality of life.

Study design

Delayed gastric emptying: according to ISGPS-criteria (International Study Group of Pancreatic Surgery).

Gastric emptying rate:

1. 1 week before operation;

2. 7th postoperative day;

Quality of life:

1. Before operation;

2. 2, 4 and 12 weeks after operation.

Intervention

1. Antecolic route of gastroenteric anastomosis after pancreatoduodenectomy;

2. Retrocolic route of gastroenteric anastomosis after pancreatoduodenectomy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Planned explorative laparotomy for suspected pancreatic or periampullary disease, with intention of resection;

2. Age >/= 18 yrs;

3. Willing and able 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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-03-2009
Enrollment:	182
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-03-2009
Application type:	First submission

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
NTR-new	NL1613
NTR-old	NTR1697
Other	Medical Ethics Committee of the Academic Medical Center, Amsterdam : 09/005
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A