Closure of the Pancreatic Remnant after Distal Pnacreatectomy A prospective randomized controlled trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24836

Source
NTR

Brief title
CPR

Health condition

chronic pancreatitis, cystic pancreatic lesions, malignant pancreatic lesions and neuroendocrine tumors located in the body or tail of the pancreas.

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Pancreas research fonds

Intervention

Outcome measures

Primary outcome

development of pancreatic fistula

Secondary outcome

mortality

morbidity

costs

Study description

Background summary

Inappropriate closure of the pancreatic remnant after distal pancreatectomy remains a common source

of morbidity. Pancreatic fistula and leakage are the most common and clinically relevant complications,

and they are thought to depend on surgical technique and skill. A variety of procedures have been

recommended to reduce the frequency of pancreatic fistula. Results of previously described techniques

after pancreatico-duodenectomy suggest that outcome with regard to pancreatic fistula can be

improved using a fibrinogen/thrombin coated collagen patch (TachoSil) in carrying out pancreatico-

jejunostomy. The CPR trial will compare a standard method of hand- or stapled closure of the pancreatic

remnant with or without the use of a collagen patch. If the collagen patch is effective in reducing

pancreatic fistula and overall morbidity it has potential to improve quality of life and reduce medical

costs.

Study objective

Determine which technique for sealing of the pancreatic remnant after distal pancreatectomy optimally closes the pancreatic remnant, leading to the lowest incidence of pancreatic fistula.

Study design

screening

day of surgery

day 10 post-operative

day 30 post-operative

6 months post-operative

12 months post-operative

Intervention

placement of a collagen patch on the sutured or stapled pancreatic remnant, with a sutured/stapled closed pancreatic remnant as control.

Contacts

Public
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Eligibility criteria

Inclusion criteria

- Age above 18 years

- Expected survival time more than 12 months

- WHO Karnofsky performance status >50% / ASA I-II

- Patients with chronic pancreatitis, cystic pancreatic lesions, malignant pancreatic lesions and neuroendocrine tumors located in the body or tail of the pancreas.

- patients who are planned to undergo distal pancreatectomy as part of an extensive resection for other malignancies (i.e. sarcoma, GIST, gastric carcinoma).

- written informed consent

Exclusion criteria

- Current immunosuppresive therapy

- Chemotherapy within 2 weeks before operation

- Curative resection not feasable

- Severe psychiatrric or neurologic disease

- Drug and/or alcohol abuse

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	250
Type:	Actual

Ethics review

Positive opinion

Date:	08-09-2016
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	NL5876
NTR-old	NTR6048
Other	NL29396.078.09 : MEC-2009-347

Study results