

The effectiveness of adding Braun anastomosis to Standard Child reconstruction to reduce delayed gastric emptying after pancreatoduodenectomy (REMBRANDT): a multicenter randomized-controlled trial.

Published: 14-02-2023

Last updated: 24-05-2024

To assess the effectiveness of adding BE in reducing DGE in patients undergoing open pancreatoduodenectomy.

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

Summary

ID

NL-OMON56185

Source

ToetsingOnline

Brief title

REMBRANDT TRIAL

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym

pancreas cancer, pancreas head carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: grant toegewezen door Rising Tide Foundation

Intervention

Keyword: Braun enteroenterostomy, Delayed Gastric Emptying, Pancreatoduodenectomy, Patient reported outcome measures

Outcome measures

Primary outcome

Incidence of DGE Grade B/C (according to International Study Group of Pancreatic Surgery (ISGPS))

Secondary outcome

Incidence of postoperative pancreatic fistulas (POPF) Grade B/C (according to ISGPS), anastomotic leak (HJ, BE), complications, hospital length of stay, functional outcome at 12 months, in-hospital mortality, 30-day mortality. Healthcare costs.

Study description

Background summary

The addition of Braun enteroenterostomy reduces the incidence of delayed gastric emptying (DGE) resulting in lower morbidity and healthcare costs after pancreatoduodenectomy.

Study objective

To assess the effectiveness of adding BE in reducing DGE in patients undergoing open pancreatoduodenectomy.

Study design

A multicenter, patient and observer blinded, registry-based randomized-controlled trial.

Intervention

Braun enteroenterostomy (BE), or Braun anastomosis, in addition to usual care.

Study burden and risks

Patients undergoing open pancreatoduodenectomy have an increased risk of postoperative complications such as DGE, POPF and anastomotic leak. The addition of BE, which is an anastomosis, could also result in a leak. However, this risk is diminishable compared to the risks of DGE and DGE related other complications like HJ and PJ anastomotic leaks associated with standard pancreatoduodenectomy. Moreover, previous cohort studies involving BE do not describe an increased risk of adverse outcomes for BE.

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

- undergoing open pancreatoduodenectomy
- provided informed consent
- age over 18 years

Exclusion criteria

- insufficient control of the Dutch language to read the patient information and to fill out the questionnaires in Dutch hospitals
- insufficient control of the Italian language to read the patient information and to fill out the questionnaires in Italian hospitals
- Previous bariatric surgery (such as Roux-en-Y gastric bypass, gastric sleeve)
- Pregnancy
- Bowel motility disorders
- Minimally invasive pancreatoduodenectomy
- Gastric outlet obstruction

Study design

Design

| | |
|---------------------|-------------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

Recruitment

NL

| | |
|---------------------------|------------|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 17-04-2023 |
| Enrollment: | 256 |
| Type: | Actual |

Ethics review

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|--------------------|--------------------------------------|
| Approved WMO | |
| Date: | 14-02-2023 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO | |
| Date: | 04-05-2023 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO | |
| Date: | 17-10-2023 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO | |
| Date: | 13-12-2023 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

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 | NL82918.091.22 |