

PANDA-trial.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20546

Source

Nationaal Trial Register

Health condition

pancreas, pancreaticoduodenectomy, postoperative recovery, complications

Sponsors and support

Primary sponsor: University Medical Centre Maastricht

Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

1. Need for radiological or surgical drainage;
2. Overall complications.

Secondary outcome

1. Postoperative length of hospital stay;
2. Functional recovery;

3. Mortality;
4. Readmission.

Study description

Background summary

Randomized controlled trial to assess the need for prophylactic drainage after pancreaticoduodenectomy.

Study objective

We hypothesized that avoidance of drainage after pancreaticoduodenectomy leads to less secondary interventions, less complications and a reduction in length of hospital stay.

Study design

3 years duration of the study.

Intervention

Control group (group A): Conventional prophylactic drainage applied adhering to routine protocols, drain removal on POD 4;

Study group (group B): No prophylactic drainage after surgery.

Contacts

Public

Department of Surgery

Maastricht University Medical Centre

P.O. Box 5800
R.M. Dam, van
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3876543

Scientific

Department of Surgery

Maastricht University Medical Centre

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R.M. Dam, van
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3876543

Eligibility criteria

Inclusion criteria

1. Diagnosis of pancreas head tumour;
2. Elective Pancreaticoduodenectomy;
3. Age > 18 years;
4. ASA I / II / III;
5. Written informed consent.

Exclusion criteria

1. Emergency surgery;
2. ASA IV / V;
3. Impossibility to obtain informed consent;
4. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control: Active

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-03-2012

Enrollment: 360

Type: Anticipated

Ethics review

Not applicable

Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 39246

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3076
NTR-old	NTR3224
CCMO	NL37950.068.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39246

Study results

Summary results

Conlon, K.C., et al., Prospective randomized clinical trial of the value of intraperitoneal drainage after pancreatic resection. Ann Surg, 2001. 234(4): p. 487-93; discussion 493-4.