Drain vs geen drain na pancreasstaartresectie

Gepubliceerd: 11-12-2020 Laatst bijgewerkt: 15-05-2024

The objective of the PANDORINA trial is to evaluate the non-inferiority of omitting routine intra-abdominal drainage after DP on postoperative morbidity (Clavien-Dindo score ≥ 3), and, secondarily, POPF grade B/C.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Lever en galwegen therapeutische verrichtingen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28212

Bron
NTR

Verkorte titel
PANDORINA

Aandoening

- Lever en galwegen therapeutische verrichtingen

Aandoening

Ductal adenocarcinoma, mucinous cystic neoplasm, intraductal papillary mucinous neoplasm, neuroendocrine tumor, solid-pseudopapillary neoplasms, chronic pancreatitis.

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Ethicon
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

- Chirurgische ingreep

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint is the rate of Clavien-Dindo score ≥ 3 complications

Toelichting onderzoek

Achtergrond van het onderzoek
Prophylactic abdominal drainage is current standard practice after distal pancreatectomy (DP), with the aim to divert pancreatic fluid in case of a postoperative pancreatic fistula (POPF) aimed to prevent further complications as bleeding. Whereas POPF after pancreatoduodenectomy, by definition, involves infection due to anastomotic dehiscence, a POPF after DP is essentially sterile since the bowel is not opened and no anastomoses are created. Routine drainage after DP could potentially be omitted and this could even be beneficial because of the hypothetical prevention of drain-induced infections (Fisher, 2018). Abdominal drainage, moreover, should only be performed if it provides additional safety or comfort to the patient. In clinical practice, drains cause clear discomfort. One multicenter randomized controlled trial confirmed the safety of omitting abdominal drainage but did not stratify patients according to their risk of POPF and did not describe a standardized strategy for pancreatic transection. Therefore, a large pragmatic multicenter randomized controlled trial is required, with prespecified POPF risk groups and a homogeneous method of stump closure.

Doel van het onderzoek
The objective of the PANDORINA trial is to evaluate the non-inferiority of omitting routine intra-abdominal drainage after DP on postoperative morbidity (Clavien-Dindo score ≥ 3), and, secondarily, POPF grade B/C.

Onderzoeksopzet
Patients undergoing elective DP will be randomly allocated in a 1:1 ratio to no prophylactic abdominal drainage or prophylactic abdominal drainage after surgery, stratified based on the risk of POPF. This protocol was developed according to the SPIRIT guidelines [20]. Total inclusion time of the study is planned to be 24 months from start of recruitment and the total study time 36 months. The study structure includes setup of sites (4–6 months), enrollment (24–30 months), and data analysis and reporting results (4 months).

In case of readmission related to surgery within 90 days after initial discharge, follow-up for secondary outcomes will be extended to the entire duration of readmission.

Onderzoeksproduct en/of interventie
Omitting abdominal drainage after distal pancreatectomy

Inschatting van belasting en risico
PANDORINA is the first binational, multicenter, randomized controlled non-inferiority trial with the primary objective to evaluate the hypothesis that omitting prophylactic abdominal drainage after DP does not worsen the risk of postoperative severe complications [18, 19]. The focus of this study is to assess if operative placed drains lead to less complicated POPF which need a reintervention or reoperation. However, POPF B/C without intervention cannot be measured in the no drain arm of our study since this is because of prolonged operative drainage. Therefore, the primary endpoint is chosen to be severe morbidity, while this is caused by a POPF grade B/C, on which the clinical focus will lie. Most of the published studies on drain placement after pancreatectomy focus on both pancreatoduodenectomy and DP, but these two entities present are associated with different complications and therefore deserve separate evaluation [29, 30]. The PANDORINA trial is innovative since it takes the preoperative risk on POPF into account based on the D-FRS and it warrants homogenous stump closing by using the same graded compression technique and same stapling devive [22, 24].

Contactpersonen

Publiek

Amsterdam UMC
Eduard Antonie van Bodegraven

0641469544

Wetenschappelijk

Amsterdam UMC
Eduard Antonie van Bodegraven

0641469544

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder

65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Elective distal pancreatectomy, >18 years of age, all indications, all approaches (open, laparoscopic, robotic).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Pregnancy, DP as a secondary procedure during gastric or colonic resection, Colonic resection required for cancer extension (gastric resection allowed), Participation to another study with interference with study outcome;

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Preventie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	06-10-2020
Aantal proefpersonen:	282
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO

Datum:	05-10-2020
Soort:	Eerste indiening
Toetsingscommissie:	MEC Academisch Medisch Centrum (Amsterdam)
	Kamer G4-214
	Postbus 22660
	1100 DD Amsterdam
	020 566 7389
	mecamc@amsterdamumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55011
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9116
CCMO	NL72237.018.20
OMON	NL-OMON55011

Resultaten