# Prophylactic abdominal drainage or no drainage after distal pancreatectomy (PANDORINA): a binational multicenter randomized controlled trial

Published: 11-12-2020
Last updated: 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.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Hepatobiliary therapeutic procedures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON28212

**Source**
NTR

**Brief title**
PANDORINA

### Condition

- Hepatobiliary therapeutic procedures

**Synonym**
Pancreatic lesions

**Health condition**

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

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Ethicon
**Source(s) of monetary or material Support:** None

## Intervention

- Surigical procedure

**Explanation**

## Outcome measures

**Primary outcome**

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

**Secondary outcome**

Secondary outcomes are grade B/C POPF, re-operation, catheter drainage, abdominal collections, wound infection, DGE, PPH, blood transfusion, length of stay (LOS), in-hospital mortality, 30-day mortality, 90-day mortality, readmission within 30 days, start of adjuvant chemotherapy.

# Study description

**Background summary**
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.

**Study objective**
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.

**Study design**
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.

**Intervention**
Omitting abdominal drainage after distal pancreatectomy

**Study burden and risks**
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].

# Contacts

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# Eligibility criteria

**Age**
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

## Inclusion criteria

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

## Exclusion criteria

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;

# Study design

## Design

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|---|---|
| Study phase: | N/A |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Prevention |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 06-10-2020 |
| Enrollment: | 282 |
| Type: | Actual |

## IPD sharing statement

**Plan to share IPD:** No

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 05-10-2020 |
| Application type: | First submission |
| Review commission: | MEC Academisch Medisch Centrum (Amsterdam)<br>Kamer G4-214<br>Postbus 22660<br>1100 DD Amsterdam<br>020 566 7389<br>mecamc@amsterdamumc.nl |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 55011
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

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

# Study results