

# Intra-abdominal drainage for two days versus no DRAINage following PANcreas resection

**Submission date**  
27/06/2007

**Recruitment status**  
No longer recruiting

Prospectively registered

Protocol

**Registration date**  
06/07/2007

**Overall study status**  
Completed

Statistical analysis plan

Results

**Last Edited**  
31/12/2020

**Condition category**  
Injury, Occupational Diseases, Poisoning

Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
EK-BR-23/07-1

## Study information

**Scientific Title**  
Intra-abdominal drainage for two days versus no DRAINage following PANcreas resection

**Acronym**  
PANDRA

## **Study objectives**

The hypothesis of the present study is that a short-time (two days) abdominal drainage does not decrease the rate of re-interventions after pancreas resection. Therefore it is not necessary to place an intra-abdominal drainage.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics approval received from the Sächsische Landesärztekammer Ethics Committee on the 20th June 2007 (ref: EK-BR-23/07-1).

## **Primary study design**

Interventional

## **Study design**

Prospective, pre-operatively randomised controlled trial performed as a parallel group design.

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Pancreas resection

## **Interventions**

Each participant will be randomised to one of the following two groups:

Intervention group: intra-abdominal drainage for two days following pancreas resection

Control group: no drainage following pancreas resection

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

The rate of re-interventions (operative and interventional) after pancreas resection.

## **Key secondary outcome(s)**

The following will be monitored for 14 days after operation:

1. Surgical overall morbidity
2. Pancreatic fistula
3. Intra-abdominal abscess
4. Mortality

## **Completion date**

31/12/2010

## **Eligibility**

**Key inclusion criteria**

1. Age equal or above 18 years
2. Patients with resectable malignancies of the pancreas
3. Patients with benign tumours of the pancreas
4. Patients with chronic pancreatitis
5. Patients with other rare indications for pancreatic resection (i.e., bleeding)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Lower age limit**

18 Years

**Sex**

All

**Total final enrolment**

438

**Key exclusion criteria**

1. Patients with a cardiac infarction within six months before operation
2. Chemotherapy within eight weeks before operation
3. Malignancy that has not responded to treatment within five years before operation
4. Lack of compliance
5. Pregnancy
6. Participation in another trial with interference of intervention or outcome

**Date of first enrolment**

01/07/2007

**Date of final enrolment**

31/12/2010

**Locations****Countries of recruitment**

Germany

**Study participating centre**

Hospital of Dresden-Friedrichstadt

Dresden

Germany

01067

## Sponsor information

### Organisation

Hospital of Dresden-Friedrichstadt (Germany)

### ROR

<https://ror.org/035xba693>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Hospital of Dresden-Friedrichstadt (Germany)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2016	31/12/2020	Yes	No