ISRCTN04937707 https://doi.org/10.1186/ISRCTN04937707

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

Submission date	Recruitment status
27/06/2007	No longer recruiting
Registration date	**Overall study status**
06/07/2007	Completed
Last Edited	**Condition category**
31/12/2020	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Helmut Witzigmann

Contact details
Hospital of Dresden-Friedrichstadt
Department of General and Visceral Surgery
Friedrichstrasse 41
Dresden
Germany
01067

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).

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

Primary study design
Interventional

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?
Results article	results	01/09/2016	31/12/2020	Yes	No