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Distal Pancreatectomy: a randomised controlled trial to compare two different surgical techniques

Submission date
18/07/2006

Recruitment status
No longer recruiting

Registration date
26/07/2006

Overall study status
Completed

Last Edited
02/06/2011

Condition category
Digestive System

[X] 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

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Additional identifiers

Protocol serial number
SDGC 01/2004

Study information

Scientific Title

Acronym
DISPACT-Trial

Study objectives
The trial is designed to show that the risk of developing a pancreatic fistula and/or death until day seven after the surgical procedure can be reduced by stapler-closure of the pancreatic remnant compared to scalpel transsection and hand-sewn suture following distal pancreatectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethikkommission der Medizinischen Fakultät Heidelberg on the 10th August 2006 (1st vote), 28th August 2006 (final vote), 4th October 2006 (Amendment I), 26th January 2007 (Amendment II) (ref: 245/2006).

Primary study design
Interventional

Study design
A multi-centre (20 international centres), pre-operatively randomised, controlled and patient and observer blinded trial performed as a parallel group adaptive superiority design.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diseases of the pancreatic body and tail

Interventions
Distal pancreatectomy:
1. Experimental group: stapler resection
2. Control group: scalpel resection and hand-suture of the pancreatic stump

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The combined primary endpoint is the presence of a pancreatic fistula and/or death due to any cause on day seven post-operatively.

Key secondary outcome(s)
1. Operating time
2. Frequencies of burst abdomen, wound infection, and intra-abdominal fluid collection and abscess
3. Post-operative length of hospital stay

4. New onset of diabetes mellitus
5. One-year survival

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Age equal or above 18 years
2. Expected survival time more than 12 months
3. Patients with at least one of the following pathologic diseases scheduled for elective resection:
3.1. Resectable malignancies of the pancreatic body and/or tail
3.2. Resectable chronic pancreatitis of the body and/or tail
3.3. Resectable benign tumours of the pancreas including neuroendocrine tumours
3.4. Resectable pseudocyst of the pancreatic body and/or tail

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Current immunosuppressive therapy
2. Chemotherapy within two weeks before operation
3. Radiotherapy within eight weeks before operation
4. Curative resection is not feasible
5. Severe psychiatric or neurologic diseases
6. Drug and/or alcohol abuse according to local standards
7. Participation in another intervention trial with interference of intervention or outcome
8. Inability to follow the instructions given by the investigator or interviewer
9. Expected lack of compliance
10. Lack of informed consent

Date of first enrolment
01/12/2006

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

Germany

Italy

Netherlands

Slovenia

Sweden

Switzerland

Study participating centre
Department of General, Visceral and Trauma Surgery
Heidelberg
Germany
69120

Sponsor information

Organisation
University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Heidelberg (Universitätsklinikum Heidelberg) (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	26/07/2009		Yes	No
Results article	results	30/04/2011		Yes	No