

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

<b>Submission date</b> 18/07/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/06/2011	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Markus W. Büchler

**Contact details**  
Department of General, Visceral and Trauma Surgery  
Im Neuenheimer Feld 110  
Heidelberg  
Germany  
69120  
+49 (0) 62 2156 6986  
[markus.buechler@med.uni-heidelberg.de](mailto:markus.buechler@med.uni-heidelberg.de)

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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 transection 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).

## 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.

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/12/2006

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

A total of approximately 450 patients will be randomised

**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**

Germany

Italy

Netherlands

Slovenia

Sweden

Switzerland

United Kingdom

**Study participating centre**

**Department of General, Visceral and Trauma Surgery**

Heidelberg

Germany

69120

## **Sponsor information**

**Organisation**

University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

**Sponsor details**

Study Centre of the German Surgical Society (SDGC)  
Department of General, Visceral and Trauma Surgery  
Im Neuenheimer Feld 110  
Heidelberg  
Germany  
69120  
+49 (0)62 2156 6986  
sdgc@med.uni-heidelberg.de

**Sponsor type**

University/education

**Website**

<http://www.sdgc.de>

**ROR**

<https://ror.org/013czdx64>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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	26/07/2009		Yes	No
<a href="#">Results article</a>	results	30/04/2011		Yes	No