

A prospective randomised clinical trial for closure of the pancreatic remnant following distal pancreatectomy

Submission date 09/07/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/07/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
7/2001

Study information

Scientific Title

Study objectives

Pancreatic fistula and intra-abdominal fluid collection are the most common complications of distal pancreatectomy. Our aim is to compare post-operative complication rates of the techniques of the closure of the pancreatic stump such as the simple stapling or the combined method of covering the stapled stump with a seromuscular patch of the jejunum.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Committee of Science and Research Ethics. Date of approval: 20/11/2001 (ref: 76-1-73 /A/09)

Study design

Prospective randomised single-centre clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pancreatic fistula and/or intra-abdominal fluid collection

Interventions

Distal pancreatectomy was performed in both groups. In the control group the pancreatic stump was closed by a stapler. In the intervention group the pancreatic remnant was first closed by a stapler then covered by a seromuscular patch of the jejunum.

The total duration of follow-up was 3 months in both groups.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The rate of post-operative pancreatic fistula and intra-abdominal fluid collection. The 3-month post-operative period was analysed.

Key secondary outcome(s)

1. The rate of re-interventions, either surgical or radiological
2. Length of hospital stay

The 3-month post-operative period was analysed.

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. Aged 18 to 80 years, either sex
2. Distal pancreatectomy is indicated because of a benign or malignant tumour of the pancreas, chronic pancreatitis or malignant neoplasm of other organs infiltrating the pancreas, provided the parenchyma of the pancreas is suitable for stapling

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Aged under the age of 18 or over the age of 80 years
2. Too thick or wide parenchyma of the pancreas
3. Death in the first 72 hours of the post-operative period

Date of first enrolment

01/01/2002

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Hungary

Study participating centre

Petz Aladar Teaching Hospital

Gyor

Hungary

9024

Sponsor information

Organisation

Petz Aladar Teaching Hospital (Hungary)

ROR

<https://ror.org/03vqk1b90>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Petz Aladar Teaching Hospital (Hungary)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration