

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

Contact name
Prof Attila Olah

Contact details
Petz Aladar Teaching Hospital
Vasvari P. u. 2.
Gyor
Hungary
9024

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

The 3-month post-operative period was analysed.

Overall study start date

01/01/2002

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

70 patients

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)

Sponsor details

PO Box 92

Gyor

Hungary

9024

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Petz Aladar Teaching Hospital (Hungary)

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