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The greater omental flap to cover the cut surface of the liver for prevention of delayed gastric emptying after left-sided hepatobiliary resection

Submission date
12/01/2010

Registration date
19/01/2010

Last Edited
20/01/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
N/A

Study information

Scientific Title

The greater omental flap to cover the cut surface of the liver for prevention of delayed gastric emptying after left-sided hepatobiliary resection: a prospective randomised controlled trial

Study objectives
The use of the greater omental flap to cover the cut surface of the liver is effective in reducing the incidence of delayed gastric emptying (DGE) after left-sided hepatobiliary resection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Human Research Review Committee of the Nagoya University Hospital approved on the 21st May 2007

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Delayed gastric emptying

Interventions
Patients were randomised to undergo left-sided hepatobiliary resection
1. With greater omental flap to cover the cut surface of the liver
2. Without greater omental flap

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Clinical grading of DGE based on the International Study Group of Pancreatic Surgery (ISGPS) classification. DGE was classified with regard to the duration of naso-gastric tube (NGT) requirement and/or need for re-insertion of NGT, and the postoperative day (POD) when solid food intake was tolerated after surgery. To assess DGE, once solid food intake was stablised, a radiopaque marker was administered. Abdominal X-rays were taken 1, 2, 3, 4, 5, and 6 hours after the administration of the marker.

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Patients scheduled to undergo left-sided hepatobiliary resection for cholangiocarcinoma at the Nagoya University Hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients scheduled to undergo other gastrointestinal resection, including hepatopancreaticoduodenectomy
2. Previous gastrointestinal resection
3. Aged over 20 years, either sex

Date of first enrolment
01/06/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Japan

Study participating centre
65, Tsurumai-cho, Showa-ku
Nagoya
Japan
466-8550

Sponsor information

Organisation

Nagoya University Graduate School of Medicine (Japan) - Division of Surgical Oncology, Department of Surgery

ROR
https://ror.org/00ndx3g44

Funder(s)

Funder type
University/education

Funder Name
Nagoya University Graduate School of Medicine (Japan) - Division of Surgical Oncology, Department of Surgery

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration