ISRCTN65426707 https://doi.org/10.1186/ISRCTN65426707

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

Contact name
Dr Tsuyoshi Igami

Contact details
65, Tsurumai-cho, Showa-ku
Nagoya
Japan
466-8550
igami@med.nagoya-u.ac.jp

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet (in Japanese)

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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2007

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

Age group
Adult

Sex
Both

Target number of participants
40 patients

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

Sponsor details
65, Tsurumai-cho,
Showa-ku
Nagoya
Japan
466-8550

Sponsor type
University/education

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

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