

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/01/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/01/2010	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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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 stabilised, 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