

A novel laparoscopic pancreaticogastrostomy technique

Submission date 13/12/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/09/2015	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A pancreaticoduodenectomy is a surgical procedure performed to treat pancreatic cancer. It typically involves removing the head of the pancreas, a portion of the duodenum (first part of the small intestine) and other organs. Although many procedures are routinely performed via keyhole (laparoscopic) surgery, pure laparoscopic pancreaticoduodenectomy (LPD) is not because of the technical difficulty in removing the head of the pancreas (pancreatic resection) and the following reconstruction procedures. Here, we want to present a novel easy reconstruction technique and its safety.

Who can participate?

Patients requiring laparoscopic pancreaticoduodenectomy who agree to be treated with the new technique.

What does the study involve?

A new laparoscopic reconstruction technique is performed on five participants undergoing a pancreaticoduodenectomy.

What are the possible benefits and risks of participating?

There are no benefit or risks associated with taking part in the trial.

Where is the study run from?

Toranomon Hospital (Japan)

When is the study starting and how long is it expected to run for?

January 2012 to December 2013

Who is funding the study?

Toranomon Hospital research committee (Japan)

Who is the main contact?

Dr Kazunari Sasaki

Contact information

Type(s)

Scientific

Contact name

Dr Kazunari Sasaki

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Pancreaticogastrostomy in pure laparoscopic pancreaticoduodenectomy - a novel pancreatic-gastric anastomosis technique

Study objectives

To validate new technique safety

Ethics approval required

Old ethics approval format

Ethics approval(s)

Human ethical committee of Toranomom hospital

Study design

Single center prospective

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Pancreas or papillary of Vater tumor requiring pancreaticoduodenectomy

Interventions

We tested the operative method safety and reproducibility of our new laparoscopic reconstruction technique.

Duration of observation was 7.7–15.5 months. (total duration of observation and follow-up are the same)

Intervention Type

Procedure/Surgery

Primary outcome measure

Mortality and morbidity.

We evaluated outcome from just after operation to most recent outpatient clinic visit.

Secondary outcome measures

N/A

Overall study start date

01/01/2012

Completion date

31/12/2013

Eligibility**Key inclusion criteria**

Patients requiring laparoscopic pancreaticoduodenectomy who agree with using the new technique

Participant type(s)

Other

Age group

All

Sex

Both

Target number of participants

5

Key exclusion criteria

N/A

Date of first enrolment

01/01/2012

Date of final enrolment

31/12/2013

Locations

Countries of recruitment

Japan

Study participating centre**Toranomon Hospital**

2-2-2 Toranomon Minato-ku

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Sponsor information

Organisation

Toranomon Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05rkz5e28>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Toranomon Hospital research committee (Japan)

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/07/2015		Yes	No