Long term effect of bile duct injury in gallbladder surgery.

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Evaluation of quality of life and resoration of function after bile duct injury.

Ethical review	Approved WMO
Status	Completed
Health condition type	Gallbladder disorders
Study type	Observational invasive

Summary

ID

NL-OMON31215

Source
ToetsingOnline

Brief title
bile duct injuy

Condition

- Gallbladder disorders
- Hepatobiliary therapeutic procedures

Synonym
bile duct injury

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: eigen vermogen

Intervention

Keyword: bile duct, functional outcome, injury, quality of life

Outcome measures

Primary outcome

Quality of life

Funtional outcome

Secondary outcome

Stenosis bile duct

Study description

Background summary

The incidence of bile injury after cholectstectomy is <2%. The treatment of the injury depends on the type and time of diagnosis of the injury. If detected peroperatively low morbidity and mortality rates have been reported. However if the diagnosis is made postoperatively there is significant morbidity and mortality.
A number of studies have researched the functional outcome and quality of life after bile duct injury. However these studies were mainly conducted in referral centres that specialise in HPB-surgery. Therefor a selectionbias exsist. Also most studies were conducted a decenia ago when endoscopic treatment was not available is all hospitals. The currenct study is conducted is a high volume hospital. Therfor it is possible to select a relevant group of patients over a relative short period of time (2003-2006) with treatment of bile duct injury performed on modern standards.
Since most patients have been discharged from further follow up and no intervention has been planned only studies that are a minimal burden to the patient have been selected, ie bloodanalysis and ultrasound.

Study objective

Evaluation of quality of life and resoration of function after bile duct injury.

Study design

Patient groups are selected from a historical database. Type of operation, type of injury and type of reconstruction will we analysed retrospectively. All other data will be collected prospectively.

Studies planned:
Ultrasound liver en bile duct
Blood analysis

Quality of life: SF-36 and GI0QLI questionnaire

Study burden and risks

Burden only in time. Minimal invasive studies have been selected: blood analysis (1x) and abdominal ultrasound.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Basicgroup: bile duct injury after cholecystectomy
Controlgroup: uncomplicated cholecystectomy

Exclusion criteria

laparotomy for different cause

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-12-2007
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	25-06-2007
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL17449.096.07