

Long term effects on quality of life after bile duct injury due to cholecystectomy.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24283

Source

Nationaal Trial Register

Brief title

COBACH II

Health condition

Bile duct injury
Cholecystectomy
Quality of life

Galwegletsel
Cholecystectomie
Kwaliteit van leven

Sponsors and support

Primary sponsor: Atrium Medical Center, Heerlen, The Netherlands

Source(s) of monetary or material Support: Atrium Medical Center, Heerlen, The Netherlands

Intervention

Outcome measures

Primary outcome

Quality of Life:

1. SF-36 score;
2. GI-QLI score.

Secondary outcome

N/A

Study description

Background summary

Background of the study:

Bile duct injury (BDI) is a serious complication after cholecystectomy. Many studies on quality of life (QoL) after BDI have been performed in tertiary referral settings. This study investigates QoL after BDI by cholecystectomy in a large teaching hospital. Four years ago, we conducted the COBACH study which investigated the short-term QoL in patients with BDI one year after cholecystectomy. In the present study (COBACH II) we will investigate the long term QoL in the same patients at least five years after cholecystectomy.

Objective:

To investigate the effect of BDI after cholecystectomy on long term QoL.

Design:

This is a retrospective study in which all patients who participated in the COBACH study will be contacted to participate. They were selected from a database of all patients who underwent a cholecystectomy between January 2003 and December 2007. Patients were divided between a BDI and a control group. Controls were randomly selected and matched on age, gender, indication, planning and operating method with the BDI group. For this study a total of 17 BDI patients and 34 control patients will be contacted.

Population:

Adults who underwent a cholecystectomy at the Atrium Medical Center, Heerlen, the Netherlands.

Intervention:

All patients will be asked to fill in the Study 36-item Short Form Health Survey (SF-36) and the Gastrointestinal Quality of Life Index (GI-QLI) questionnaires. Both are recommended by the European Association for Endoscopic Surgery to assess QoL in patients with gallbladder disease. The SF-36 is a 36 item questionnaire suitable for self-administration that includes a multi-item scale (ranging from 0 to 100) which assesses eight concepts: Physical Functioning; Social Functioning; Role-Physical Functioning; Role-Emotional Functioning, Bodily Pain; Mental Health; Vitality; and General Health. It also measures Change in Health over one year, although this is not included in one of the eight subscales. In addition, the eight subscales can be clustered to calculate the Physical Component Summary (PCS) and Mental Component Summary (MCS) which each represent four of the SF-36 subscales together to get a more general idea of the patient's physical and mental QoL. The GI-QLI is a system-specific questionnaire useful for self-administration to assess QoL in patients with gastro-intestinal disease. It generates an overall measurement of QoL as well as QoL in four subscales: Gastro-intestinal symptoms; physical functioning; social functioning; and emotional functioning.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

This study has a low burden for participating patients. A time investment of a maximum of 30 minutes has to be made to fill in and return the questionnaires. Patients do not have to come to the hospital but can return the questionnaire by mail.

There are no risks for patients participating in this study.

Study objective

Long term quality of life of patients with iatrogenic bile duct injury due to cholecystectomy is lower than in patients with an uncomplicated cholecystectomy.

Study design

5 years after cholecystectomy.

Intervention

1. Questionnaire: Medical Outcome Study 36-item Short Form Health Survey (SF-36);
2. Questionnaire: Gastrointestinal Quality of Life Index (GI-QLI).

Contacts

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Eligibility criteria

Inclusion criteria

Both groups:

1. Cholecystectomy in the Atrium Medical Centre Heerlen with at least five years of follow-up;
2. Age ≥ 18 ;
3. Participation in the COBACH I study (1-year quality of life).

Bile duct injury group:

1. Iatrogenic bile duct injury after cholecystectomy.

Control group:

1. Uncomplicated cholecystectomy.

Exclusion criteria

1. Admission to another hospital due to bile duct injury;
2. Other abdominal surgery not related to bile duct injury after cholecystectomy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	21-08-2012
Enrollment:	51
Type:	Anticipated

Ethics review

Positive opinion	
Date:	19-08-2012
Application type:	First submission

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
NTR-new	NL3435
NTR-old	NTR3586
Other	METC Atrium-Orbis-Zuyd : 12-N-79
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A