

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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24283

Bron

NTR

Verkorte titel

COBACH II

Aandoening

Bile duct injury
Cholecystectomy
Quality of life

Galwegletsel
Cholecystectomie
Kwaliteit van leven

Ondersteuning

Primaire sponsor: Atrium Medical Center, Heerlen, The Netherlands

Overige ondersteuning: Atrium Medical Center, Heerlen, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of Life:

1. SF-36 score;

2. GI-QLI score.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

5 years after cholecystectomy.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	21-08-2012
Aantal proefpersonen:	51
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	19-08-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A