

# Burden of ERCP; Preferences for treatment of common bile duct stones

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The aim of this study is: 1) to determine the burden of ERCP in patients undergoing ERCP (descriptive study) and 2) to determine patients preferences for treatment strategy of CBDS (Discrete Choice Experiments).

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bile duct disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31173

### Source

ToetsingOnline

### Brief title

BEP study

### Condition

- Bile duct disorders

### Synonym

bile duct disease; common bile duct stones

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Burden, Common bile duct stones, ERCP, Preferences

## Outcome measures

### Primary outcome

Part I:

Burden of ERCP

Part II:

Patient preferences for CBDS treatment

### Secondary outcome

Part I:

Physical symptoms (throat ache, nausea etc), quality of life and functional results (Bilirubine, ALAT, ASAT etc).

Part II:

The relevance and importance of determinants of patient preferences for CBDS treatment (characteristics of the treatment options, and respondent characteristics)

## Study description

### Background summary

At the Erasmus MC Rotterdam, yearly 750 ERCPs and at the University Medical Center Utrecht, yearly 350 ERCPs are performed. An ERCP is an invasive procedure that is burdensome to patients and is associated with anxiety and discomfort. In addition, patients may have recurrent symptoms, requiring a reintervention, which may increase the burden of ERCP.

Common bile duct stones (CBDS) are the most common indication for ERCP. Currently, two endoscopic treatment strategies are available for the removal of CBDS. First, an endoscopic sphincterotomy (ES) followed by a cholecystectomy

can be performed for the treatment of CBDS. Second, stone extraction by ERCP can be followed by a wait-and-see policy.

Currently, the patient preference for CBDS treatment is unknown. In addition, nothing is known on the experienced health status. Do the advantages of an invasive ERCP or CBDS treatment compensate for its disadvantages? The treatment for CBDS seems to depend on the preference of the physician. Knowledge on the burden of ERCP and patient preferences for CBDS treatment may contribute to the improvement of counseling patients undergoing ERCP and/or treatment for CBDS.

## **Study objective**

The aim of this study is: 1) to determine the burden of ERCP in patients undergoing ERCP (descriptive study) and 2) to determine patients preferences for treatment strategy of CBDS (Discrete Choice Experiments).

## **Study design**

Multicenter, prospective observational study with 7-day follow-up, subdivided in part I (burden of ERCP), part II (patient preferences for treatment modalities of CBDS).

## **Study burden and risks**

Part I:

Patients will fill in a burden of ERCP questionnaire on day 1. Physical symptoms will be measured during 7 day follow-up after ERCP, by means of (telephone) interviews on day 0, 1 and 7.

Filling in all questionnaires during the 7-day follow up will take 20 minutes of time.

Part II:

Patients will fill in a questionnaire on preferences for CBDS treatment on day 0. Filling in this questionnaire will take 15 minutes.

## **Contacts**

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Part I: Burden of ERCP

a) Patient is undergoing an ERCP at the Erasmus MC-University Medical Center Rotterdam or University Medical Center Utrecht

b) Informed consent

Part II: Patient preference for common bile duct stone (CBDS) treatment

a) Patient is undergoing an ERCP for CBDS

b) Patient is referred from the Erasmus MC-University Medical Center Rotterdam or University Medical Center Utrecht

c) Patient participates in Part I

d) Informed consent

### Exclusion criteria

Part I: Burden of ERCP

a) Patient is referred from another hospital

b) Not being able to fill out the questionnaire

Part II: Patient preference for CBDS treatment

a) Patient is referred from another hospital

b) Not able to fill in the questionnaire

c) Comorbid disease (e.g. malignancy, terminal illness, WHO performance score of 4)

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-10-2007

Enrollment: 300

Type: Actual

## Ethics review

Approved WMO

Date: 21-09-2007

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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

CCMO

### ID

NL17558.078.07