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).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bile duct disorders
Study type	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 quationnaire 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

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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	ID
CCMO	NL17558.078.07