

# Sensitivity of cholangioscopy directed biopsies versus brush cytology in patients with malignant bileduct stenosis

Published: 14-04-2008

Last updated: 10-05-2024

Aim of this study is to assess the value of cholangioscopic directed biopsies versus brush cytology in differentiating between malignant and benign biliary strictures. Determination of tumor markers to improve early diagnosis of malignant biliary...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal stenosis and obstruction
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON31613

### Source

ToetsingOnline

### Brief title

(COCYSTENS-study)

### Condition

- Gastrointestinal stenosis and obstruction
- Bile duct disorders
- Hepatobiliary neoplasms malignant and unspecified

### Synonym

bileduct stenosis, bileduct stricture

### 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:** bileduct stenosis, biopsy, brush cytology, cholangioscopy

## Outcome measures

### Primary outcome

1. The difference in sensitivity between brush cytology en cholangioscopic directed biopsy for detection of patients with malignant biliary stricture.
2. Cholangioscopic aspect of stricture

### Secondary outcome

Duration of examination

## Study description

### Background summary

It is important to differentiate between malignant and benign bile duct stenoses. Direct tissue sampling with brush cytology yields low sensitivity rates that makes this method insufficient for definitive treatment decisions. New cholangioscopes and biopsy forceps are developed. Aim of this study is to assess the value of cholangioscopic directed biopsies versus brush cytology in differentiating between malignant and benign biliary strictures. Also, we want to collect extra tissue, plasma and fecal samples for determination of tumor markers.

### Study objective

Aim of this study is to assess the value of cholangioscopic directed biopsies versus brush cytology in differentiating between malignant and benign biliary strictures.  
Determination of tumor markers to improve early diagnosis of malignant biliary strictures.

### Study design

prospective study

## Study burden and risks

Patients have got indications for ERCP and the cholangioscopic examination is an extra supplement to the diagnostic proces. No extra sessions are necessary. The subjects will be emitted in the hospital for two days. ERCP has got risks such as bleeding, perforation and post-ERCP pancreatitis.

No extra examinations, hospital or outpatients visits are necessary.

## Contacts

### Public

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NL

### 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

Age  $\geq$  18 year  
icterus (bilirubine  $>2 \times \text{ULN}$ )  
Cholestasis (GGT or alk fos  $>2 \times \text{ULN}$ )  
dilated bile ducts on imaging with abdominal ultrasound, CT, or MRI

## Exclusion criteria

Distal CBD stenosis  
Clinical conditions that do not allow ERCP with sphincterotomy such as uncorrectable coagulopathies  
High suspicion of common bile duct stones  
Patients unable or not willing to give informed consent

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 08-05-2008

Enrollment: 30

Type: Actual

## Ethics review

Approved WMO

Date: 14-04-2008

Application type: First submission

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

Approved WMO	
Date:	05-06-2008
Application type:	Amendment
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	NL17488.078.07