Diagnostic Accuracy Of Different Cholangioscopy-Guided Biopsy Techniques For The Diagnosis Of Indeterminate Biliary Strictures

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25153

Source
Nationaal Trial Register

Brief title
Biopsy

Health condition

Indeterminate biliary stricture

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

Sensitivity, specificity and accuracy

Secondary outcome

Adverse events

Study description

Background summary

Single-operator cholangioscopy has shown promising results for detection of cholangiocarcinoma in indeterminate biliary strictures, with higher sensitivity rates for diagnosis through direct stricture visualisation suggested as compared to targeted biopsies. Biopsy protocols and tissue sampling techniques such as bite-on-bite biopsies for diagnosing indeterminate biliary strictures have not yet been systematically investigated. The diagnostic accuracy of tissue sampling by taking multiple biopsies and using the bite-on-bite technique will be investigated

Study objective

Both biopsy techniques are equally feasible

Study design

If benign pathology on biopsies, 1 year FU

Intervention

Multiple cholangioscopy-guided random biopsies and bite-on-bite(-on-bite) biopses of an indeterminate biliary stricture

Contacts

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Eligibility criteria

Inclusion criteria

- Male or female > 18 years old
- Presence of an indeterminate biliary stricture, defined as:
1. A bile duct stricture or filling defect of indeterminate nature after previous laboratory work-up, abdominal imaging (MRI, CT, endoscopic ultrasound) or ERCP, and/or;
2. Negative or inconclusive cytology or histology after ERCP with brush cytology or intra-ductal biopsies, and/or;
3. Despite benign cytology or histology findings persistent strong suspicion of a malignant aetiology based on clinical symptoms such as abdominal pain, unexpected weight loss, loss of appetite and obstructive jaundice.
- Written informed consent

Exclusion criteria

- Contraindication for ERCP or SOC (i.e. suspicion of ascending cholangitis or of acute pancreatitis)
- Contraindication for biopsy (i.e. known coagulation disorder)
- No written informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-11-2020

Enrollment:	75
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date:	11-08-2021
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	NL9649
Other	METC EMC : MEC-2018-1639

Study results