ERCP BRush cytology of pancreatobiliary strictures – Infinity versus Boston Scientific RX cytology brush: a randomized controlled trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25595

Source
NTR

Brief title
BRIX

Health condition

Pancreatobiliary stricture suspicious for malignancy
Pancreatobiliaire stricturen verdacht voor maligniteit

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Investigator initiated

Intervention

Outcome measures

Primary outcome

The main study endpoint is the difference in sensitivity of brush cytology between the standard RX cytology brush and the Infinity cytology device.

Secondary outcome

- Diagnostic performance

- Cellular yield

- Complication rate, such as bleeding, cholangitis or pancreatitis

Study description

Study objective

We hypothosize that the sensitivity of the Infinity cytology device (US Endoscopy,Northeast Ohio, USA) is higher compared to the RX Cytology brush (Boston scientific Corporation, Marlborough, MA, USA) in patients with pancreatobiliary stricture suspicious for malignancy.

Study design

T = 0 ERCP

T = 7 days (telephone)

T = 30 days (telephone)

T = 6 months (patient records)

Intervention

During ERCP biliary brushing will be performed with either standard RX cytology brush (group 1) or the Infinity cytology device (group 2).

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Eligibility criteria

Inclusion criteria

- Patients with pancreatobiliary stricture suspicious for malignancy

• Who are planned to undergo ERCP with biliary brush cytology

OR

• Who are planned to undergo ERCP with biliary stent placement for (suspected) malignant strictures

- ≥18 years old

- Written informed consent

Exclusion criteria

- Inability to cannulate the papilla

- Hilar biliary obstruction, defined as stenosis located within 2 cm of the hilum

- Not fulfilling standard criteria to undergo ERCP with biliary brush according to local guidelines

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2015
Enrollment:	106
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL5234
NTR-old	NTR5458
Other	METC AMC Amsterdam : METC 2015_240

Study results