

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

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To compare the sensitivity of ERCP brush cytology between standard RX cytology brush and Inifinity brush in patients with pancreatobiliary strictures suspicious for malignancy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Observational invasive

Summary

ID

NL-OMON50220

Source

ToetsingOnline

Brief title

BRIX

Condition

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

Synonym

Pancreatobiliary strictures; extrahepatic stricture

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Brush cytology, Cholangiocarcinoma, Pancreatic carcinoma, Pancreatobiliary stricture

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

Background summary

Pancreatobiliary strictures are a difficult diagnostic challenge since they can be either malignant or benign. Endoscopic retrograde cholangiopancreatography (ERCP) with biliary brushing and cytology analysis is often used for diagnostic purposes, but the sensitivity of this procedure is low ($\pm 42\%$). Recent studies showed that the sensitivity of brush cytology can be improved to 75-78% when using the Infinity cytology device (US Endoscopy, Northeast Ohio, USA).

Study objective

To compare the sensitivity of ERCP brush cytology between standard RX cytology brush and Infinity brush in patients with pancreatobiliary strictures suspicious for malignancy.

Study design

Randomized controlled trial

Study burden and risks

Both brushes are being used in clinical practice, but it is unknown if the risk of complications is comparable. Apart from the standard risks of ERCP, the risk of complications of endoscopic brush cytology is very low. Compared to the Boston brush, the bristles of the Infinity brush are more stiff. It is unclear if the brush design will lead to a higher number of complications. Because of this design, sphincterotomy will always be performed when using the Infinity brush. If the Boston brush is being used, the endoscopist can decide if a sphincterotomy will be performed. The main risks for endoscopic sphincterotomy are haemorrhage (2%) and perforation (0.3%).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

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:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2016
Enrollment:	112

Type: Actual

Medical products/devices used

Generic name: Infinity cytology device and RX Cytology brush
Registration: Yes - CE intended use

Ethics review

Approved WMO
Date: 14-01-2016
Application type: First submission
Review commission: METC Amsterdam UMC

Approved WMO
Date: 25-02-2020
Application type: Amendment
Review commission: METC Amsterdam UMC

Approved WMO
Date: 24-03-2020
Application type: Amendment
Review commission: METC Amsterdam UMC

Approved WMO
Date: 16-02-2021
Application type: Amendment
Review commission: METC Amsterdam UMC

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
Other	NL5234
CCMO	NL54762.018.15