The use of SPEctroscopy during Endoscopy for Detection of BiLIary Strictures

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Primary:- The feasibility of SFR spectroscopy incorporated in an ERCP procedure.Secondary:- Determine physiological differences between benign and malignant biliary strictures, based on the obtained spectra acquired over a broad wavelength range (...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON48022

Source
ToetsingOnline

Brief title
SPEEDBLIS trial

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
bile duct cancer, biliary strictures

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF Bas Mulder Award (grant UL2015-7665)

Intervention

Keyword: 1) biliary strictures, 2) Endoscopic retrograde cholangiopancreatography, 3) spectroscopy, 4) endoscopy

Outcome measures

Primary outcome

As this is a feasibility study, the main parameter is the (percentage of) cases in which SFR spectroscopy was possible to measure the reflectance during ERCP procedure.

Secondary outcome

The shape of the spectra and the optical absorption coefficients over a broad wavelength range will be used to distinguish benign and malign biliary strictures. To extract and quantify physiological information from the obtained spectra validated mathematical model, based on the knowledge of the absorption spectra of the chromophores, will be used. The extracted parameters are:

1) Microvascular saturation

2) Blood volume

3) Average vascular diameter

4) Parameter related to the scattering properties of tissue in real-time.

The parameters will be linked to final histological analysis.

Study description

Background summary

Distinguishing benign and malignant biliary strictures is often difficult.

Around 70% of the biliary strictures have a malignant origin, whereas up to 30% of the strictures were benign. Because of the choice of treatment, differentiating benign from malign strictures is very important. The routine work-up consists of obtaining clinical information and abdominal imaging (ultrasound, CT, MRCP). However, brush cytology and tissue biopsies, acquired during endoscopic retrograde cholangiopancreatography (ERCP), are usually necessary for adding more information about the possible diagnosis. Brush cytology alone yields to a mean sensitivity of 42%, whereas the specificity approaches 95%. Brush cytology and forceps biopsy combined, yield to an increased sensitivity between 60-70% in detecting of malignant structures. Nevertheless, the sensitivity in differentiating benign from malignant biliary strictures is still not reliable enough and that states the need for improved techniques. A novel technique in detecting tumor tissue is Single Fiber Reflectance (SFR) spectroscopy, which could be incorporated in the EUS-FNA procedure to detect pancreatic masses. It is an optical imaging technique, capable of extracting reflectance spectra from endogenous chromophores from a very small tissue volume. In a feasibility study of our group, SFR spectroscopy showed an accurate correlation between cytology in 9 patients with a pancreatic mass (3 benign vs 6 malignant). Moreover, the oxygen saturation and bilirubin concentration differs significantly between normal and malignant tissue. In this study, the feasibility of SFR spectroscopy incorporated in an ERCP procedure for distinguishing benign and malignant biliary strictures will be evaluated by measuring wavelength dependent optical characteristics over a broad wavelength range (400-1000 nm).

Study objective

Primary:
- The feasibility of SFR spectroscopy incorporated in an ERCP procedure.
Secondary:
- Determine physiological differences between benign and malignant biliary strictures, based on the obtained spectra acquired over a broad wavelength range (400-1000 nm).

Study design

Prospective observational single center feasibility study.

Study burden and risks

No additional risks were expected during participation in this study, besides the standard risks for ERCP. The optical measurements are performed with sterile optical fibers. To avoid potential spread of tumor cells to healthy tissue, measurements are only taken in tissue that will be removed by biopsies. The total time taken by the measurements is around 5 minutes.

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 scheduled for ERCP, due to indeterminate biliary strictures.

Exclusion criteria

- Patients with age under 18 years
- Patients who object to participate in this study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Single fiber reflectance spectroscopy
Registration:	No

Ethics review

Approved WMO

Date:	26-07-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL68521.058.19