The use of SPEctroscopy during Endoscopy for Detection of PANcreatic Cancer

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Primary Objective: - The ability of SFR spectroscopy incorporated in EUS-FNA procedure in distinguishing benign and malignant pancreatic tissue by measuring wavelength dependent optical characteristics over a broad wavelength range (400-1000 nm)....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON50186

Source
ToetsingOnline

Brief title
SPEEDPANC

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

Synonym
pancreatic cancer, pancreatic lesions

Health condition

pancreas

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Horizon 2020 grant: ASTONISH (project ID: 692470)

Intervention

Keyword: optical imaging, pancreas, pancreatic tumors, spectroscopy

Outcome measures

Primary outcome

The shape of the spectra and the optical absorption coefficients over a broad wavelength range will be used to distinguish pancreatic tumors and benign pancreatic tissue. To extract and quantify physiological information from the obtained spectra, such as blood volume fraction and tissue oxygenation, a validated mathematical model, based on the knowledge of the absorption spectra of the chromophores, will be used. Therefore, we need to determine the serum bilirubin and hemoglobin, before the EUS-FNA is performed, which is part of the clinical workflow ('zorgpad pancreas'). The obtained spectra will be linked to final cytological analysis.

Secondary outcome

The diagnostic accuracy (including sensitivity, specificity, negative predictive value and positive predictive value) of one or more combined wavelengths specific for pancreatic tumor tissue will be calculated after comparison to cytological and final diagnosis.

Study description

Background summary

Even with the current imaging modalities there are still limitations in the diagnosis of pancreatic cancer. EUS-FNA is the least invasive and most effective procedure in diagnosing pancreatic tumors. A disadvantage of EUS-FNA is the relatively long period, approximately three weeks between procedure and diagnosis of the pancreatic mass and the lack of specificity, which sometimes requires the EUS-FNA procedure to be repeated. 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 (55% vs. 21%, p=0.038; 166 µmol/L vs. 17 µmol/L, p=0.039, respectively). In this study SFR spectroscopy, incorporated in the EUS-FNA procedure, will be evaluated to increase the diagnostic accuracy and to facilitate the diagnosis of pancreatic cancer.

Study objective

Primary Objective:
- The ability of SFR spectroscopy incorporated in EUS-FNA procedure in distinguishing benign and malignant pancreatic tissue by measuring wavelength dependent optical characteristics over a broad wavelength range (400-1000 nm).

Secondary Objective:
- Selection of wavelengths specific for pancreatic tumor detection and evaluation of its diagnostic accuracy compared to cytological diagnosis.

Study design

This study is designed as a prospective observational multicenter study.

Study burden and risks

There is no benefit for the individual patient upon participation to this study. The benefit will concern a large amount of the future pancreatic cancer population. However, there are also minimal risks for the patients participating in this study. The use of sterile products minimises the risk of infection, during the procedure. Measurements are taken only in tissue that will directly afterwards be removed, to avoid potential spread of tumor cells to normal pancreatic tissue. The burden is also minimal: the patients are already subjected to the EUS-FNA procedure. The total additional time of the

measurements is expected to be 10 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 EUS-FNA, due to a suspect lesion of the pancreas

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:	Recruiting
Start date (anticipated):	07-03-2019
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	Single Fiber spectroscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-06-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	02-11-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	29-08-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-12-2020
Application type:	Amendment
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	NL63777.058.17