Feasibility of the Integration of Single Fiber Reflectance Spectroscopy during Endoscopic Ultrasound-Guided Fine Needle Aspiration in Pancreatic Masses

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Primary Objective: Evaluation of the potential of the incorporated SFR spectroscopy into the EUS-FNA procedure to discriminate benign and malignant pancreas tissue in vivo.Secondary Objective: To measure the wavelength dependent differences in...

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

Summary

ID

NL-OMON40241

Source
ToetsingOnline

Brief title
SFR-PanMas

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

Synonym
pancreatic mass, tumour

Health condition

Pancreasafwijkingen

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: CTMM Musis 25018

Intervention

Keyword: DPS, Optical properties, Pancreas, Spectroscopy

Outcome measures

Primary outcome

Shape of the spectra obtained from spectroscopy, optical absorption coefficient

of the different types of pancreatic tissue, cytological results and the

endosonographic images during the EUS-FNA procedure and during the surgery.

Secondary outcome

Patient characteristics: age, diagnosis, tumour size.

Study description

Background summary

Pancreatic cancer is the fourth leading cause of cancer deaths, leading to 227.000 deaths worldwide yearly. The five year survival rate is only 4%. Approximately 1750 new patients were diagnosed with pancreatic cancer in The Netherlands in 2006. Late detection is the most important cause for the low survival percentage, because pancreatic cancer is mainly presented by clinically silent symptoms[1]. In case of presenting symptoms, abdominal pain or mid-back pain, weight loss and jaundice are reported[2].

The misdiagnosis of pancreatic tumours can be avoided by preoperative biopsies, ultrasound (US), computed tomography (CT), endoscopic retrograde cholangiopancreatography (ERCP), or by endoscopic ultrasound-guided fine needle aspiration (EUS-FNA). In recent literature, the sensitivity and specificity of EUS-FNA vary widely, sensitivity of 92% (95% CI = 91-92%, $p < 0.001$) and specificity of 96% (95% CI = 93-98%, $p = 0.006$)respectively[3]. The

disadvantage of EUS-FNA are the long period, approximately three weeks between procedure and diagnosis of the pancreatic mass and many procedures need to be repeated, because the results, based on aspirated cytology, are not reliable enough.

A novel alternative method to assess pancreatic tumours is EUS-FNA with an incorporated fiber optical reflectance device, Single Fiber Reflectance (SFR) spectroscopy. SFR is capable of extracting biologically relevant parameters, believed to be relevant for cancer diagnosis, from a very small tissue volume. Reflectance spectra obtained by SFR spectroscopy contain information about tissue absorption and scattering properties. To facilitate measurements of these parameters during endoscopic ultrasound guided fine needle aspiration procedures, we will use a fiberoptic probe that fits in the needle of a standard EUS-FNA device[4].

Similar procedures have been tested clinically in mamma carcinoma, cerebral carcinomas and mediastinal lymph nodes at the Erasmus MC, Rotterdam, The Netherlands. These results showed a significantly reduced oxygen saturation in tumours compared to normal tissue. [4, 5] In the proposed study, we will extend these measurements to pancreatic masses during an EUS-FNA procedure. It is important to obtain measurements in healthy pancreatic tissue as well, in order to compare them to measurements in tumor tissue. Therefor we will perform measurements in the same patients during surgery as well.

References

1. Vincent, A., et al., Pancreatic cancer. The Lancet. 378(9791): p. 607-620
2. Petersen, G.M., et al., Pancreatic Cancer Genetic Epidemiology Consortium. Cancer Epidemiology Biomarkers & Prevention, 2006. 15(4): p. 704-710
3. Chen, J., et al., Diagnostic accuracy of endoscopic ultrasound-guided fine-needle aspiration for solid pancreatic lesion: a systematic review. J Cancer Res Clin Oncol, 2012. 138(9): p. 1433-41
4. Kanick SC, v.d.L.C., Aerts JG, Hoogsteden HC, Kascáková S, Sterenborg HJ, Amelink A, Integration of single-fiber reflectance spectroscopy into ultrasound-guided endoscopic lung cancer staging of mediastinal lymph nodes. J Biomed Opt, 2010. 15(1)
5. Kanick SC, v.d.L.C., Djamin RS, Janssens AM, Hoogsteden HC, Sterenborg HJ, Amelink A, Aerts JG, Characterization of mediastinal lymph node physiology in vivo by optical spectroscopy during endoscopic ultrasound-guided fine needle aspiration. J Thorac Oncol, 2010. 5(7): p.981-7

Study objective

Primary Objective:
Evaluation of the potential of the incorporated SFR spectroscopy into the EUS-FNA procedure to discriminate benign and malignant pancreas tissue in vivo.

Secondary Objective:
To measure the wavelength dependent differences in optical properties between benign and malignant pancreatic tissue over a broad wavelength range (400-900 nm).

Study design

Feasibility study

Study burden and risks

No additional risks, besides the standard risks for EUS-FNA and pancreatic surgery, are associated with participation. The burden and risks associated with participation are minimal; optical measurements are performed with sterile optical fibers. Measurements are only taken in tissue that will be removed by cytology or surgery. The total time taken by the measurements is less than 10 minutes for each procedure, so less than 20 minutes in total.. The patients will not benefit from the study.

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 a pancreatic mass undergoing EUS-FNA and pancreatic surgery.

Exclusion criteria

Objection to participation

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):	03-11-2014
Enrollment:	12
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	19-03-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	11-09-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	29-10-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Not approved Date:	04-12-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	13-01-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL46072.058.13