Contrast-enhanced harmonic endoscopic ultrasound for pancreatic mass lesions

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON34952

Source
ToetsingOnline

Brief title
Contrast EUS

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Pancreas "mass"; Pancreas "tumor"

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Contrast, Endoscopic ultrasound, Pancreas

Outcome measures

Primary outcome

Descriptions of the contrast-enhanced vascular perfusion patterns of solid pancreatic mass lesions, and the correlations to the histological diagnoses obtained from FNA or subsequent surgery. This will enable derivation of the sensitivity, specificity, positive predictive value and negative predictive value of each contrast harmonic EUS image pattern for the different solid lesions in the pancreas.

Secondary outcome

n/a

Study description

Background summary

Endoscopic ultrasound (EUS) is the best imaging modality for characterizing focal lesions within the pancreas. However, differentiating between solid pancreatic lesions by EUS imaging alone can be challenging. Currently, exclusion of malignant disease requires histology from a fine needle aspiration of the lesion, but this too is not always entirely definitive.
Contrast-enhanced harmonic EUS is a new technology that offers the potential for improved diagnostic capabilities, and may help to more reliably discriminate between benign and malignant lesions.

Study objective

The purpose of this study is to characterize the contrast enhancement patterns on EUS of different solid lesions in the pancreas, and to determine the correlations of these contrast-enhanced EUS findings with the histological gold standard obtained by fine needle aspiration or subsequent surgery.

Study design

Prospective, observational cohort study.

Study burden and risks

Participation in the study only involves receiving the contrast agent Sonovue with additional imaging with special ultrasound software during an already scheduled EUS procedure. Thus, no additional procedures or interventions other than the administration of a commercially available, non-experimental contrast agent are required. The alternative for patients who decline is to simply undergo conventional EUS without contrast enhancement followed by EUS-guided FNA. No follow-up visits or additional tests are required of study participants unless dictated by ongoing clinical care, which is separate from the study. The risk of study participation is the rare possibility of an allergic-type reaction to Sonovue. The immediate benefit of study participation is expected improved visualization of the pancreatic mass lesion. The greater benefit from the study is the hope for improved diagnostic capabilities with EUS that may in future enable better differentiation of lesions in the pancreas and may ultimately obviate the need for tissue sampling in some patients.

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

1) Adult patient 18 years or older.
2) Able to read & write in Dutch.
3) Undergoing EUS for the evaluation of a solid pancreatic lesion.

Exclusion criteria

1) Cystic pancreatic lesion.
2) Known allergy to Sonovue (contrast agent).
3) Unstable ischemic heart disease (contra-indication to Sonovue).

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):	12-07-2010
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	29-06-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL30457.078.09