Contrast-enhanced endoscopic ultrasound versus CT scan in the evaluation of focal pancreatic lesions.

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The study is designed to assess the diagnostic value of contrast agents on endosonographic images during the evaluation of focal pancreatic lesions.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON35110

Source
ToetsingOnline

Brief title
CE-EUS versus CT scan in pancreatic lesions

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
pancreatic tumor; pancreatic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: eigen research pot

Intervention

Keyword: contrast enhanced endoscopic ultrasound, CT-scan, pancreatic lesions

Outcome measures

Primary outcome

Determine the sensitivity of contrast enhanced EUS

Secondary outcome

Compare the sensitivity of contrast enhanced EUS with that of CT scan

Study description

Background summary

Cancer of the exocrine pancreas is the fourth leading cause of cancer-related death in the United States and is the fifth leading cause of death among all malignancies, leading to approximately 40,000 deaths each year in Europe. Surgical resection is the only potentially curative treatment. The operation is considered major with high morbidity and mortalitiy risk.
Focal pancreatic lesions can be benign in nature, potentially malignant, or malignant. Therefore it is essential to characterize the nature of focal pancreatic lesions and select patients accordingly for operation.
Imaging techniques such as CT scans are widely used for the evaluation of these lesions. Endoscopic ultrasound (EUS) may be useful for diagnosis of small tumors (eg, less than 2 to 3 cm in diameter) and helpful for evaluating the possibility of nodal and major vascular involvement. It has been reported that the sensitivity of EUS is equal or even superior to that of multidetector-row CT.
Ultrasound contrast agents are a new class of agents used during ultrasound examinations that can be used to improving the diagnostic capability of US to detect or characterize focal lesions and to obtain better visualization of the blood vessels and perfusion.
The basis of these contrast agents is gas microbubbles, small enough to cross the lung bed to produce systemic enhancement after an intravenous injection. Among fluoro-gas*containing agents that use phospholipids as the membrane, the most experience in contrast enhanced-EUS in clinical practice has been made with Sonovue (Bracco, Milan).

Study objective

The study is designed to assess the diagnostic value of contrast agents on endosonographic images during the evaluation of focal pancreatic lesions.

Study design

100 individuals will be requested to participate in the study over an inclusion period of 1 year. During EUS procedure, a 5 ml of contrast agent Sonovue will be administered. EUS images will be examined for the presence of enhancement. The final diagnosis will be based on clinical presentation plus
1. the results of serum and fluid analysis (obtained by aspirating cystic lesions) for lipase, albumin, and tumor markers
2. the results of radiological and endoscopic examinations
3. the results of cytological examination of samples obtained by fine needle aspiration
4. the results of histological examination of specimens removed surgically
The contrast enhanced EUS findings will be analysed to investigate its value in diagnosis of focal pancreatic lesions and compare this value with that of CT scan.

Intervention

A contrast agent will be administred intravenously

Study burden and risks

Adverse events that can arise after administration of ultrasound contrast agents secondary to toxicity, generation of biologic effects, embolism, and anaphylasis. An assessment by the European Committee for Medical Ultrasound Safety concluded that the toxic and embolic potential of a ultrasound contrast agents is of no clinical significance.
There is a risk of allergic reactions, mostly mild, e.g. transient rashes or a sensation of warmth, but they may be very sever, e.g. dyspnea, bradycardia, or hypotension.
Premature ventricular ectopic beats can be elicited. There have been reported cardiac deaths in patients with ischemic heart disease when undergoing contrast enhanced stress echo studies. The regulatory authorities have issued a recommendation that the agents implicated (e.g. Sonovue) not be used in patients with unstable ischemic heart disease.

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

Individuals with focal pancreatic lesions documented by CT scan

Exclusion criteria

Patients with unstable coronary artery disease
Known allergy to SonoVue

Study design

Design

Study phase:	4
Study type:	Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	SonoVue
Generic name:	Sulphur hexafluoride
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	07-10-2010
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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
EudraCT	EUCTR2010-018672-25-NL
CCMO	NL31537.101.10