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# The utility of the Contrast Enhanced endoscopic ultrasound in guiding fine needle aspiration for PANcreatic masses

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| **Submission date**<br>26/03/2013 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>08/08/2013 | **Overall study status**<br>Completed | |
| **Last Edited**<br>18/01/2019 | **Condition category**<br>Cancer | |

## Plain English summary of protocol

Background and study aims
The global accuracy of fine needle aspiration endoscopic ultrasound (EUS-FNA) for detecting pancreatic adenocarcinoma (cancer of the pancreas) is about 85%. The use of contrast agents (dyes) during EUS may highlight the vessels and the diseased (necrotic) parts of the pancreatic masses, which could lead to obtaining larger and less bloody pancreatic samples.
The aim of the study is to evaluate whether the guidance of fine needle aspiration (FNA) during harmonic contrast-enhanced pancreatic endoscopic ultrasound (CEH-EUS) would increase the diagnostic accuracy of FNA guided by conventional endoscopic ultrasound (EUS) in the same pancreatic masses.

Who can participate?
Both male and female patients, above 18 years old with pancreatic mass.

What does the study involve?
In each prospectively examined patient with pancreatic masses on CT scan, EUS- FNA was performed using a 22 G needle, followed by CEH-EUS using Sonovue as contrast agent. A second cluster of EUS-FNA was performed on contrast image, avoiding vessels and the regions inside the mass considered as necrosis. The final diagnosis was based on the results of EUS-FNA and surgery, or 6 months of follow-up in benign lesions.

What are the possible benefits and risks of participating?
The CEH-EUS allows a better orientation of the needle inside the pancreatic lesion during FNA and possibly increases the yield of diagnostic accuracy in pancreatic masses. There are no risks over normal EUS-FNA of pancreatic masses.

Where is the study run from?
University of Medicine and Pharmacy Cluj Napoca, Romania.
Regional Institute of Gastroenterology and Hepatology Cluj Napoca.

When is the study starting and how long is it expected to run for?
The study started in March 2013 and ran until May 2013.

Who is funding the study?
National Olympus and Aloka-Hitachi.

Who is the main contact?
Andrada Seicean, MD, PhD.

# Contact information

### Type(s)
Scientific

### Contact name
Dr Andrada Seicean

### Contact details
15, Closca street
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400039

# Additional identifiers

### Protocol serial number
N/A

# Study information

### Scientific Title
The utility of the Contrast Enhanced endoscopic ultrasound in guiding fine needle aspiration for PANcreatic masses

### Acronym
CEPAN

### Study objectives
The use of the contrast agents during endoscopic ultrasound (EUS) may highlight the vessels and the necrotic parts of the pancreatic masses, which could better to guide sampling.

The aim of the study is to evaluate whether the guidance of fine needle aspiration (FNA) during harmonic contrast-enhanced endoscopic ultrasound of the pancreas would increase the diagnostic accuracy of FNA than FNA guided by conventional endoscopic ultrasound (EUS) in the same pancreatic masses.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

Ethics Board of the Regional Institute of Gastroenterology and Hepatology Cluj-Napoca, Romania, approval 04.12.2012, ref: 15283

### Study design
Interventional non-randomized single center study

### Primary study design
Interventional

### Study type(s)
Diagnostic

### Health condition(s) or problem(s) studied
Pancreatic mass

### Interventions
This is a non-randomized study. In each prospectively examined patient with pancreatic masses on CT scan, Endoscopic Ultrasound - Fine Needle Aspiration (EUS- FNA) was performed using a 22 G needle, followed by Contrast Enhanced Harmonic Endoscopic Ultrasound (CEH-EUS) using Sonovue as contrast agent. A second cluster of EUS-FNA was performed on contrast image, avoiding vessels and the regions inside the mass considered as necrosis. The final diagnosis was based on the results of EUS-FNA and surgery, or 6 months of follow-up in benign lesions. The pairs of samples (cell blocks), obtained during conventional EUS-FNA and CEH-EUS-FNA, were assessed blindly for macroscopic and microscopic aspects by two pathologists. No cytopathologist was present in the EUS room during the procedure. Qualitative assessment of pancreatic mass after contrast injection was done compared to surrounding parenchyma.

The duration of the intervention up to 30 minutes.

The duration of follow-up - 30 minutes after the procedure

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Diagnostic accuracy of FNA guided by conventional endoscopic ultrasound (EUS)

### Key secondary outcome(s))
Combination of the time to peak obtained by quantitative assessment of the contrast image with CEH-EUS-FNA pathologic results

### Completion date
31/05/2013

## Eligibility

### Key inclusion criteria

Any gender and age above 18 years old with pancreatic mass. Pancreatic mass detected by ultrasonography or computerised tomography (CT) scan

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. History of chemotherapy
2. Coagulation disorders
3. Patients refuse

### Date of first enrolment
28/03/2013

### Date of final enrolment
31/05/2013

## Locations

### Countries of recruitment
Romania

### Study participating centre
**15, Closca street**
Cluj-Napoca
Romania
400039

## Sponsor information

### Organisation
SC Techno Electro Medical Company (Romania)

# Funder(s)

### Funder type
Industry

### Funder Name
The equipment was supported by National Olympus and Aloka-Hitachi companies

### Funder Name
Other devices and the procedures were supported by the hospital: Regional Institute of Gastroenterology and Hepatology Cluj-Napoca (Romania)

# Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/04/2017 | 18/01/2019 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |