

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

Submission date 26/03/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/08/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

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
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400039

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Diagnostic accuracy of FNA guided by conventional endoscopic ultrasound (EUS)

Secondary outcome measures

Combination of the time to peak obtained by quantitative assessment of the contrast image with CEH-EUS-FNA pathologic results

Overall study start date

28/03/2013

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40-50

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)

Sponsor details

69A Calusei street

Bucuresti

Romania

021353

Sponsor type

Industry

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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