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Fine-needle aspiration guided by endoscopic ultrasonography (EUS FNA) in pancreatic masses

Submission date
03/04/2014

Recruitment status
No longer recruiting

Registration date
29/04/2014

Overall study status
Completed

Last Edited
29/04/2014

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Fine-needle aspiration guided by endoscopic ultrasonography (EUS-FNA) is a procedure to take a sample of tissue for examination under a microscope. A thin, tube-like instrument called an endoscope with an ultrasound probe and a biopsy needle at the end is inserted through the mouth into the oesophagus (gullet). The ultrasound probe is used to bounce sound waves off internal organs and tissues to make a picture on a monitor, which helps the doctor see where to place the biopsy needle to take a sample. EUS-FNA has changed the way solid pancreatic masses are treated. The aim of this study was to compare the diagnostic accuracy of 25-gauge and a 22-gauge needles in patients with pancreatic solid masses.

Who can participate?
Adults identified to have a pancreatic mass can take part in this study.

What does the study involve?
All patients underwent EUS-FNA using both needles (22-gauge and 25-gauge). The order in which the needles were used were randomly allocated. Half of them had 22-gauge used first and the rest had 25-gauge used first. Tissue samples were analysed for accuracy of diagnosis.

What are the possible benefits and risks of participating?
It is possible that the thinner 25-gauge needle could provide equal or better performance in sampling the pancreas than the 22-gauge needle. It can possibly decrease the risk of FNA-induced bleeding and contamination of the tissue sample.

Where is the study run from?
Geneva University Hospital (Switzerland).

When is the study starting and how long is it expected to run for?
The study started in December 2010 and ran for two years.

Who is funding the study?
Geneva University Hospital (Switzerland) and Cook (Ireland).

Who is the main contact?
Prof. Jean Louis Frossard
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Contact information

Type(s)
Scientific

Contact name
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1211

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol No 09-244 accepted on 27.01.2010

Study information

Scientific Title
EUS-guided fine needle aspiration (FNA) in pancreatic masses: a prospective randomized study comparing the yield of 22-gauge and 25-gauge needle in the same patient

Acronym
EUS FNA

Study objectives
It remains unclear whether the 22- and 25-gauge needles have equal diagnostic yields in EUS-FNA of pancreatic masses.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Cantonal Commission of Research Ethics [Commission cantonale d'éthique de la recherche (CCER)], 27/01/2010, Ref. 09-244

Study design
Prospective randomized study

Primary study design
Interventional

Secondary study design
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
Pancreas mass

Interventions
EUS FNA
The randomization sequence of the needle size was created with a 1:1 allocation using blocks of four without stratification. The allocation was achieved in the operating room by physicians blinded for the allocation sequence, using sequentially numbered, sealed and opaque envelopes.

All patients undergo EUS-FNA with a 22-gauge needle and a 25-gauge needle. The order of the needles used is randomised.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Tissue sample was examined under the microscope. All slides were evaluated for the amount of blood found on the smears, digestive contamination, pancreatic cellularity and final diagnosis. The final diagnosis was based on cytology report, surgical pathology if available, repeated radiological imaging and clinical follow-up.

Secondary outcome measures
FNA complications

Overall study start date

01/12/2010

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Only adults over 18 years were eligible for the study. They all presented to our service with a solid pancreatic mass identified by at least two dissimilar imaging modalities (ultrasound, CT scan, MRI).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

Key exclusion criteria
1. Sepsis
2. Acute pancreatitis defined as abdominal pain associated with increased serum lipase > 3 the normal value)
3. Anticoagulant therapy
4. Antiaggregant therapy other than aspirin
5. Previous history of modified anatomy interfering with endoscopic assessment
6. Incapacity to give informed consent

Date of first enrolment
01/12/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Switzerland

Study participating centre

Service of Gastroenterology and Hepatology
Geneve
Switzerland
1211

Sponsor information

Organisation
Geneva University Hospital (Switzerland)

Sponsor details
c/o Prof Frossard
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Sponsor type
Hospital/treatment centre

Website
http://www.hcuge.ch

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Geneva University Hospital (Switzerland)

Funder Name
Cook (Ireland) - provided needles

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