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Endoscopic Ultrasound Guided Tissue Sampling (The ProCore Study)

Submission date	Recruitment status	[ ] Prospectively registered
28/06/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/06/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/07/2016	Digestive System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14399

Study information

Scientific Title

A multi-centre randomised trial comparing EUS guided fine needle aspiration cytology (FNAC) with fine needle aspiration biopsy (FNAB) in sampling solid pancreatic mass lesions

Acronym
The ProCore Study

Study objectives
The aim of this study is to investigate the diagnostic accuracy of the standard FNAC needle compared with the new FNAB needle in the sampling of solid pancreatic lesions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/EM/0189

Study design
Randomised interventional diagnostic accuracy trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Gastrointestinal

Interventions
Complications, Immediate complications, if any, will be recorded after the procedure. Patients will be contacted 30 days after the procedure to record any late complication.; Tissue Sampling, On the day of the procedure the patient will be consented for the procedure and for the study and will be randomised to either to obtain biopsy using 22G/25G FNAC needle citology or to obtain biopsy using 22G/25G FNAB needle. Linear and/or Radial EUS scopes will be used to identify and to take biopsy from the suspected lesion. Samples will be obtained according to the standard protocol.

According to the published data we have assumed a diagnostic accuracy of 70% using EUS-FNAC, and this to be increased to 85% using EUS-FNAB needle. To detect the difference with a p value of 0.05 (two tailed) in the two groups with 80% power we will need to recruit 134 in each group.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Diagnostic accuracy of the standard FNAC needle compared with the new FNAB needle

Secondary outcome measures
1. Adequacy of the sample obtained with the FNAC needle compared with the new FNAB needle
2. Cost analysis using the FNAC needle compared with the FNAB needle
3. Number of passes needed in obtaining adequate sample using FNAC needle compared with the FNAB needle 4. Time taken in obtaining adequate sample using the FNAC needle compared with the FNAB needle

Overall study start date
01/09/2012

Completion date
01/03/2014

Eligibility

Key inclusion criteria
1. Adult patients 18 years and above with a solid pancreatic mass of any size, needing to undergo EUS examination to collect sample for diagnosis. Definition of a solid pancreatic mass will be based on an ultrasound, CT scan or on the findings of a prior EUS.
2. Patients should have the ability and be willing to give informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 268; UK Sample Size: 268

Key exclusion criteria
1. Cystic lesions of the pancreas.
2. Patients known to be intolerant to endoscopy.
3. Patients not clinically fit for endoscopy as judged by their cariong team.
4. Patients on anticoagulation therapy.
5. Patients already participating in another trial.

Date of first enrolment
01/09/2012

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Wolfson Digestive Diseases Centre
South Block
C-Floor, Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Industry

Funder Name
Cook Medical

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