

# Endoscopic Ultrasound Guided Tissue Sampling (The ProCore Study)

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>28/06/2013   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>28/06/2013 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>15/07/2016       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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

**Protocol serial number**  
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

**Primary study design**

Interventional

**Study design**

Randomised interventional diagnostic accuracy trial

**Study type(s)**

Diagnostic

**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 cytology 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(s)**

Diagnostic accuracy of the standard FNAC needle compared with the new FNAB needle

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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 caring 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**

United Kingdom

England

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

## **Sponsor information**

**Organisation**  
University of Nottingham (UK)

**ROR**  
<https://ror.org/01ee9ar58>

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
Cook Medical

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

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