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Endoscopic ultrasound guided pancreatic tissue sampling (SharkBITE Study)

Submission date 10/04/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 02/05/2017	**Overall study status** Completed	
Last Edited 04/07/2019	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-2-needles-doctors-use-to-take-a-sample-of-pancreatic-tissue-the-sharkbite-study

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03532347

Secondary identifying numbers
33281

Study information

Scientific Title
SharkCore biopsy needle versus standard FNA needle in the diagnosis of solid pancreatic masses a randomised controlled cross-over trial of endoscopic ultrasound guided tissue acquisition - The SharkBITE study

Acronym
SharkBITE

Study objectives
The aim of this study is to compare the performance of a standard fine needle aspiration needle and the Sharkcore biopsy needle in endoscopic ultrasound guided pancreatic tissue sampling.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Newcastle & North Tyneside 1 Research Ethics Committee, 08/02/2017, ref: 16/NW/0082

Study design
Randomised; Interventional; Design type: Diagnosis, Device

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Specialty: Gastroenterology, Primary sub-specialty: Gastroenterology; UKCRC code/ Disease: Cancer/ Malignant neoplasms of digestive organs

Interventions
Adult patients with a solid pancreatic mass of any size, requiring EUS guided tissue sampling to make a diagnosis will be eligible to participate. Participants will be randomised to an initial 3 passes with Beacon FNA and then Beacon SharkCore biopsy needles or vice versa. 25g needles will be used for trans duodenal puncture and 22g for transgastric puncture. Randomisation will be via a computer generated list of allocations provided by the statistician to the trial in advance of the study. Whenever a participant is recruited the list will be referred to see what their treatment order is. All procedures will be performed/supervised by expert endosonographers. Samples will be interpreted by 2 separate groups of pathologists. The pathologists reporting the samples will be blinded to the results with the alternative device. Each participant's involvement in the study will continue for 7 days post procedure to allow for monitoring for adverse events. There will be a telephone call after 7 days to ascertain any post procedure adverse event. Study duration is envisaged as 16 months comprising 10 months recruitment and 6 months follow up.

Intervention Type
Other

Primary outcome measure
Diagnostic performance of the 2 needle types will be measured by comparing the sensitivity of standard Beacon FNA needle to the SharkCore (FNB) core biopsy needle in the sampling of solid pancreatic mass lesions.

Secondary outcome measures
1. Adequacy of the samples obtained as reported by the pathologist utilising a standard methodology
2. The duration of pathologist reporting time
3. Overall costs including device, pathology processing and pathology lab time

Overall study start date
01/04/2016

Completion date
30/11/2018

Eligibility

Key inclusion criteria
Planned Sample Size: 108; UK Sample Size: 108

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 108; UK Sample Size: 108

Key exclusion criteria
1. A greater than 50% cystic component to the pancreatic mass
2. Any contraindication to pancreatic biopsy
3. Patients with a metal biliary stent in situ and target lesion in the head of pancreas
4. Less than 18 years of age
5. Unable and unwilling to give consent
6. Unwilling to undergo additional biopsies
7. Unable to understand English
8. Pregnancy

Date of first enrolment
22/05/2017

Date of final enrolment
04/05/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
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Sponsor information

Organisation
The Newcastle Upon Tyne Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
Covidien plc

Funder Name
Medtronic Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal approximately 8 months after overall trial end date.

Intention to publish date
30/11/2019

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No