

Pan African Clinical Trials Registry

South African Medical Research Council, South African Cochrane Centre
 PO Box 19070, Tygerberg, 7505, South Africa
 Telephone: +27 21 938 0506 / +27 21 938 0834 Fax: +27 21 938 0836
 Email: pactradmin@mrc.ac.za Website: pactr.samrc.ac.za

Trial no.:		Date of Approval:	
Trial Status:			

TRIAL DESCRIPTION

Public title	EUS and EUS-guided tissue acquisition in diagnosing hepatic focal lesions
Official scientific title	Role of endoscopic ultrasound (EUS) and EUS-guided tissue acquisition in diagnosing hepatic focal lesions
Brief summary describing the background and objectives of the trial	prospective, cross-sectional study included 215 patients with pancreatic, biliary, or gastrointestinal malignancies referred for EUS examination.
Type of trial	RCT
Acronym (If the trial has an acronym then please provide)	
Disease(s) or condition(s) being studied	Cancer
Sub-Disease(s) or condition(s) being studied	
Purpose of the trial	Diagnosis / Prognosis
Anticipated trial start date	04/10/2022
Actual trial start date	02/11/2022
Anticipated date of last follow up	01/06/2023
Actual Last follow-up date	01/06/2023
Anticipated target sample size (number of participants)	215
Actual target sample size (number of participants)	
Recruitment status	Completed
Publication URL	

Secondary Ids	Issuing authority/Trial register
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STUDY DESIGN

Intervention assignment	Allocation to intervention	If randomised, describe how the allocation sequence was generated	Describe how the allocation sequence/code was concealed from the person allocating the participants to the intervention arms	Masking	If masking / blinding was used
Crossover: all participants receive all interventions in different sequence during study	Randomised	Simple randomization using a randomization table created by a computer software program	Central randomisation by phone/fax	Masking/blinding used	Participants

INTERVENTIONS

Intervention type	Intervention name	Dose	Duration	Intervention description	Group size	Nature of control
Experimental Group	EUS Sampling		one year	EUS and EUS-FNA/FNB for an assessment of pancreatic or gastrointestinal tumors without or with hepatic focal lesions detected by contrast abdominal CT or MRI.	215	

ELIGIBILITY CRITERIA					
List inclusion criteria	List exclusion criteria	Age Category	Minimum age	Maximum age	Gender
Patients with pancreatic or gastrointestinal tumors without or with hepatic focal lesions detected by contrast abdominal CT or MRI.	patients unfit for deep sedation and patients with bleeding disorders contraindicating EUS-FNA/FNB.	80 and over: 80+ Year,Adult: 19 Year-44 Year,Aged: 65+ Year(s),Middle Aged: 45 Year(s)-64 Year(s)	18 Year(s)	85 Year(s)	Both

ETHICS APPROVAL				
Has the study received appropriate ethics committee approval	Date the study will be submitted for approval	Date of approval	Name of the ethics committee	
Yes		15/08/2018	Faculty of medicine	
Ethics Committee Address				
Street address	City	Postal code	Country	
kasr al Aini street	Cairo	11451	Egypt	

OUTCOMES		
Type of outcome	Outcome	Timepoint(s) at which outcome measured
Primary Outcome	assessment of pancreatic or gastrointestinal tumors without or with hepatic focal lesions detected by contrast abdominal CT or MRI.	one week

RECRUITMENT CENTRES				
Name of recruitment centre	Street address	City	Postal code	Country
Cairo University	Kasr Al-Aini street, Cairo Egypt.	Cairo	11451	Egypt

FUNDING SOURCES				
Name of source	Street address	City	Postal code	Country
none	Kasr Al aini	Cairo	11451	Egypt

SPONSORS						
Sponsor level	Name	Street address	City	Postal code	Country	Nature of sponsor
Primary Sponsor	self	Kasr Al aini	Cairo	11451	Egypt	University

COLLABORATORS				
Name	Street address	City	Postal code	Country

CONTACT PEOPLE				
Role	Name	Email	Phone	Street address
Principal Investigator	Hussein Hassan Okasha	hussein_okasha@kasralainy.edu.eg	01001000502	Kasr Al-Aini street
City	Postal code	Country	Position/Affiliation	
Cairo	11451	Egypt	Professor	

REPORTING				
Share IPD	Description	Additional Document Types	Sharing Time Frame	Key Access Criteria
Yes	prospective, cross-sectional study included 215 Egyptian patients who were referred to the internal medicine department, Kasr Al-Aini hospitals, Cairo University for EUS and EUS-FNA/FNB for an assessment of pancreatic or	Study Protocol	prospective, cross-sectional study included 215 Egyptian patients who were referred to the internal medicine department, Kasr Al-Aini hospitals, Cairo University for EUS and EUS-FNA/FNB for an assessment of pancreatic	an assessment of pancreatic or gastrointestinal tumors without or with hepatic focal lesions detected by contrast abdominal CT or MRI.

	gastrointestinal tumors without or with hepatic focal lesions detected by contrast abdominal CT or MRI.		or gastrointestinal tumors without or with hepatic focal lesions detected by contrast abdominal CT or MRI.	
URL	Results Available	Results Summary	Result Posting Date	First Journal Publication Date
	No			
Result Upload 1:	Result Upload 2:	Result Upload 3:	Result Upload 4:	Result Upload 5:
Result URL Hyperlinks	Link To Protocol			
Result URL Hyperlinks				

Changes to trial information