

Trial Registration data set

Data category	Information ³²
Primary registry and trial identifying#	ClinicalTrials.gov NCT05055323
Date of registration in primary registry	July 6, 2021
Secondary identifying #	20F.041
Source(s) of funding	Thomas Jefferson University Hospital
Primary sponsor	Thomas Jefferson University Hospital
Secondary sponsor(s)	
Contact for public queries	HL, MD [Harish.Lavu@jefferson.edu]
Contact for scientific queries	HL, MD [Harish.Lavu@jefferson.edu]
Public title	A Study to Determine if the Drug, Pyrvinium Pamoate, is Safe and Tolerable in Patients With Pancreatic Cancer
Scientific title	<i>A Phase I Dose Escalation Study Using Pyrvinium Pamoate Targeting HuR in Pancreatic Ductal Adenocarcinoma</i>
Countries of recruitment	United States
Health condition(s) or problem(s) studied	Pancreatic ductal adenocarcinoma
Intervention(s)	Pyrvinium Pamoate (Other Name: 3546-41-6) , Given PO QD for 3 days (Dose escalation doses of 5mg/kg, 10mg/kg and 20 mg/kg)
Key inclusion and exclusion criteria	Ages eligible for study: ≥ 18 years, Sexes eligible for study: both, Accepts healthy volunteers: no
	Inclusion criteria: adult patient (≥ 18 years), Pancreatic Ductal Adenocarcinoma deemed to be candidate for curative-intent surgery. ECOG 0-1.
	Exclusion criteria: Patients with ongoing anticancer therapies, Pregnancy or currently breastfeeding, known allergic reactions to components of the study product, chronic bowel conditions, Kidney function impairment (serum creatine $> 1.5 \times$ ULN or creatine clearance ≤ 60 ml/1.73m ² fr patients with creatine levels $> 1.5 \times$ ULN). Patients with liver function impairment: Alkaline phosphatase, ALT and AST above three folds the normal limit (see normal ranges); Total Bilirubin level > 3 mg/dl; Albumin < 3 g/dl
Study type	Interventional
	Phase I
Date of first enrolment	October 29, 2021
Target sample size	18
Recruitment status	Recruiting
Primary outcome(s)	Incidence of dose limited toxicity (DLT)
Key secondary outcomes	Bioavailability of PP Fatty tissue accumulation of PP and molecular biomarkers.

