

PAN1: A randomised phase II study evaluating potential predictive biomarkers in the treatment of metastatic pancreatic cancer.

Overview: To prospectively evaluate hENT1 as a predictive marker of benefit from gemcitabine treatment in metastatic pancreatic cancer.

Study Chair: Dr Yu Jo Chua, Medical Oncologist, Canberra Hospital

Open Date: 22nd July 2011

Accrual: 0/80 patients

Trial Management Committee Members:

Yu Jo Chua	Canberra Hospital	ACT
Andrew Biankin	Garvan Institute of Medical Research	NSW
Chris Karapetis	Flinders Medical Centre	SA
Craig Underhill	Border Medical Oncology	VIC
Louise Nott	Royal Hobart	TAZ
David Goldstein	Prince of Wales Hospital	NSW
Michelle Cronk	Nambour Hospital	QLD
George Laking	Auckland Hospital	NZ
Val GebSKI	NHMRC CTC	NSW
Katrin Sjoquist	NHMRC CTC	NSW
Nicole Wong	NHMRC CTC	NSW

Study Progress:

- Received funding from the Avner Nahmani Pancreatic Cancer Research Fund.
- 20 sites are planned and 17 have been selected to date.
- 11 sites are activated to date.
- Protocol approved by Cancer Institute NSW Ethics Committee on 25/01/2011.
- Central pharmacy and oxaliplatin sourced for Australian and New Zealand sites.
- Biological testing process designed and contracts in place.
- PAN1 INFORM database designed, tested and launched live at active, participating sites.
- Internal PAN1 processes and documentation in place for site use and direction.
- Providing ongoing guidance and direction in the screening of any potential, eligible patients.
- Focus on working with New Zealand sites for additional, supplementary funding to support the conduct of the study in New Zealand.
- PAN1 AGITG Annual Scientific Meeting (ASM) presentation at the 2010 and 2011 ASMs.
- PAN1 Trials In Progress Abstract to be submitted to ASCO 2012.
- Monthly screening logs collected from all sites for ongoing monitoring of patient screening.
- Trial Management Committee (TMC) formed.
- TMC meeting held 7th November 2011 to discuss recruitment strategies. Currently organising next meeting to be held in February 2012.

Site summary:

Site Name	Activation Date	Recruitment
Canberra Hospital	22/07/2011	0
Tweed Hospital	27/07/2011	0
Royal Hobart	28/07/2011	0
Nambour	31/08/2011	0
Border Medical Oncology	22/09/2011	0
Geelong Hospital	27/09/2011	0
Townsville	27/09/2011	0
Royal North Shore	03/11/2011	0
Port Macquarie	23/11/2011	0
Flinders Medical Centre	12/12/2011	0
Royal Perth	17/01/2012	0
Christchurch Hospital	-	-
Auckland Hospital	-	-
Prince of Wales	-	-
Queen Elizabeth	-	-
Austin	-	-
Calvary Mater	-	-

Screening logs:

Site	# of Pts screened	Reasons not recruited to trial
Canberra Hospital	2	<ul style="list-style-type: none"> - The patient was ineligible for the trial as they had a previous cancer diagnosed within the past 5 years. - 1 new patient consented this week. Tissue to be sent for hENT1 testing and eligibility to then be determined.
Tweed Hospital	2	The patients were eligible however did not want to join the study.
Border Medical Oncology	6	<ul style="list-style-type: none"> - 1 patient did not have a core biopsy available and did not agree to have a core biopsy of their cancer; - 1 patient had symptomatic coronary or cardiac insufficiency; - 2 patients did not have metastatic disease; - 1 patient had bowel cancer and not pancreatic cancer; - 1 patient had disease recurrence within 6 months after completion of previous chemotherapy.
Townsville	4	<ul style="list-style-type: none"> - 1 patient did not have metastatic disease; - 1 patient did not have adequate liver function tests; - 1 patient had already commenced chemotherapy; - 1 patient had had previous chemoradiotherapy which was not radio-sensitiser dose chemotherapy.
Royal Hobart	1	The patient did not have metastatic pancreatic cancer.

Active sites not listed in table have confirmed that they have not seen any metastatic pancreatic cancer patients