Series Manual

Pancreatic Enzyme Replacement Therapy (PERT) – Series 53

Background

Globally, pancreatic cancer has a poor prognosis. A common complication of pancreatic cancer is pancreatic exocrine insufficiency (PEI), caused by the cancer directly, or functionally through blocked ducts. This lack of enzyme secretion into the duodenum often leads to malabsorption and symptoms such as bloating, wind, nausea, abdominal pain, diarrhoea and anorexia. The treatment for PEI is pancreatic enzyme replacement treatment (PERT), a biological medication administered in capsule form which aids in digestion. The timing and dosing of PERT is important and the medicine should be given at most mealtimes and with snacks.

There is evidence that PERT helps with symptom management, weight stabilisation, the ability to tolerate oncology treatments, and even survival. Studies have reported that PERT is well tolerated. However, there is also published literature highlighting the low rates of prescribing among clinicians for people with pancreatic cancer around the world. This phase IV pharmovigilance study seeks to understand clinicians' prescribing practices, and the benefits/adverse effects of PERT use in pancreatic cancer. The series will examine real clinical experience when patients with pancreatic cancer receive PERT. The aim will be to explore the use, efficacy and safety of PERT for patients with pancreatic cancer. The findings of this series may help improve prescribing practices.

Patient tracking

A log or spreadsheet should be developed in order to track the patient medical record number and the study ID number allocated to each patient when commenced on a medication/intervention. This spreadsheet will be the only link between the data collected and the identity of the patient and remains the property of the participating site. This information should not be shared with the IMPACCT Trials Coordination Centre (ITCC). The spreadsheet should also contain the date and time of the data entry at each time point.

Participant ID number	Patient name	Patient medical record number	Date of initial data entry	Time of data entry

Allocating a Participant ID (PID) number

The PID for each set of data collected is a composite number built up using a series of three codes.

i) Site identifier

This is the number allocated to each participating site as a 2- or 3-digit number. Please check with the Rapid team.

ii) Series number

The series number for PERT is 53.

iii) Participant number

This is a three-digit number starting with the first participant from 001, followed by 002, 003, and so on.

Therefore, the full patient ID number will be; ***Site identifier/medication number/patient number***
e.g., 01/53/ 001, 01/53/002…and so on.

Time points

There are 2 main time points where data is required.

1. Commencement of the medication (baseline) – (T_0)
2. 14 days post baseline – (T_1)

Other data collection points are:

1. Harm/adverse event at unexpected time points
   - There can be up to three other times where harm can be recorded (Ad hoc A, B and C)
   - These pages can be left blank if there are no unexpected harms/adverse events
2. Cessation of the medication
   - Complete this page if the medication/intervention of interest is ceased at any time during the data collection period for any reason.
3. Date of death
   - Enter the date of death if/when known.
   - If the date of death is entered during the data collection period no further prompts will be received

Each medication/intervention of interest will have different time points for clinical benefit and adverse events according to its profile. Time points are determined by each Series subcommittee and are based on clinical experience and published product information.

Adverse event assessment

Adverse events (or harms) are assessed using a standard scale from the National Cancer Institute Criteria for Adverse Events (NCI CTCAE). The NCI uses a scale between 1 and 5 ranging from mild to serious (resulting in death) symptoms or sequelae. The NCI criteria are provided as a reference document which is supplied separately and should be referred to for any events recorded is association with the patient's clinical course.

Each medication/intervention has a number of pre-populated expected adverse events (harms). These are listed at each time point, and the NCI grade is described and provided for easy reference. A grade should be provided for each listed adverse event.

If unexpected adverse events occur at any other time, either before or after any pre-determined time point, these should be recorded in the unexpected adverse event section of the case report form (Ad hoc A, B and C).

Data entry

The REDCap data entry link can be acquired by emailing **rapid@uts.edu.au** and requesting the link to the series that is applicable to you.