UTS IMPACCT Trials Coordination Centre

Series Manual

Antidepressants for Depression in Palliative Care - Series 49

What is this series about?

In the palliative care setting (especially at the very end-of-life), the assessment and management of depression can be complicated by the symptoms and complications of advanced illnesses. For example, diagnostic challenges in differentiating the symptoms of terminal illnesses from somatic symptoms of depression such as fatigue and anorexia, or intolerances to pharmacological agents.

To date, it is unclear if patients tolerate and receive actual benefit from antidepressants in real world palliative care clinical practice, particularly when life expectancy is in the range of days to weeks. This phase IV pharmacovigilance study seeks to understand clinicians' prescribing practices, and the harms and benefits of antidepressant use in the palliative care setting. The series will also compare the clinical benefits and harms of four commonly prescribed antidepressant agents in palliative care: mirtazapine, duloxetine, citalopram and escitalopram. The series will provide useful information to guide clinicians in their understanding of which antidepressant agent could be best suited for different palliative patient profiles.

Patient tracking

A log or spreadsheet should be developed in order 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.

Patient PID	Patient name	Patient medical record number	Date of initial data entry	Time of data entry

Allocating Patient ID number

a) The ID number 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 two or 3 digit number

ii) Medication number

The medication number for the Antidepressants for Depression series is **49**

iii) Patient number

This is usually a three digit number e.g. **001**

Therefore the full patient ID number will be;

Site identifier/medication number/patient number e.g., 01/**49**/001

Time points

There are 4 main time points where data is required.

1. Commencement of the medication (baseline) (T_0)
2. 7 days post baseline - (T_1)
3. 14 days post baseline – (T_2)
4. 28 days post baseline – (T_3)

Other data collection points are:

1. Harm/adverse event at unexpected time points (T_1), (T_2) and (T_3)
   - There can be up to three other times where harm can be recorded (Adhoc a, b & 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 CRF. Up to three other time points can be recorded.

Data entry

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.