



TARDIS–Working Practice Document – No: 043

Safety Monitoring

The purpose of this document is to describe actions the co-ordinating centre will take, in order to prevent and react to patients continuing on triple and dual (aspirin and clopidogrel) antiplatelet therapy beyond the maximum treatment period of 30 days, and to ensure that after 30 days, patients go back onto guideline therapy, as per local practice.

At Site Initiation Visits, we will continue to ensure that investigators understand the protocol, reinforcing the treatment period of one month, and ensure that they understand the potential hazard of long term intensive antiplatelets. We will advise sites that upon randomisation, the patient's drug chart should clearly show what the patient has been randomised to, and ensure that the treatment period of 1 month is specified.

We will remind investigators to make sure that at both baseline and day 7 face-to-face visits (whilst on treatment) patients/carers understand that the treatment is for 1 month only. A letter to the patients GP is sent as standard upon patient recruitment, to inform them of their patient's participation in the trial.

When arranging and conducting the face-to-face day 35 visit (5-7 days post treatment), we will remind investigators to make sure that patients have ceased randomised treatment and are taking guideline therapy.

The day 90 follow up is carried out via telephone, and the follow up coordinator asks questions to establish what drugs the patient is currently taking.

The trial database will be used to prevent patients remaining on triple or dual (aspirin and clopidogrel) antiplatelet therapy for longer than the maximum 30 day treatment period, by generating automatic emails which will be sent to local investigators to remind them to check that patients have reverted back to guideline therapy at the day 35 follow up visit. The day 7 and day 35 e-CRFs are also used as a tool to remind sites that patients should not be on triple or dual (aspirin and clopidogrel) therapy for longer than 30 days.

In situations where patients are recorded as being on triple or dual antiplatelet therapy (aspirin and clopidogrel) at either day 35 or day 90, the co-ordinating centre will write to the patients GP to let them know and ask them to switch the patient to guideline therapy, as per their local practice. We will also write the patient/carer directly to ask them to see their GP and switch to guideline therapy.

In addition to the actions above, the co-ordinating centre will continue to remind investigators via the newsletter and investigator meetings, about the importance of detecting prolonged triple and dual (aspirin and clopidogrel) antiplatelet therapy.