SPIRIT 2

STI571 Prospective International Randomised Trial

NEWSLETTER

December 2012

Christmas arrangements…

The **Trial Office will be closed** from 5pm on Friday 21 December to Tuesday 1 January inclusive. Any urgent queries (including medical queries) can be directed to the Chief Investigator, Prof Steve O'Brien. Contact details will be listed nearer the time under the news section on the website at www.spirit-cml.org. SAEs should continue to be reported in the normal way by fax to 0191 376 0748.

Drug orders: Any orders placed after 17 December will not be processed until Monday 7 January 2013. Please plan now for supplies that will be needed over the Christmas and New Year period.

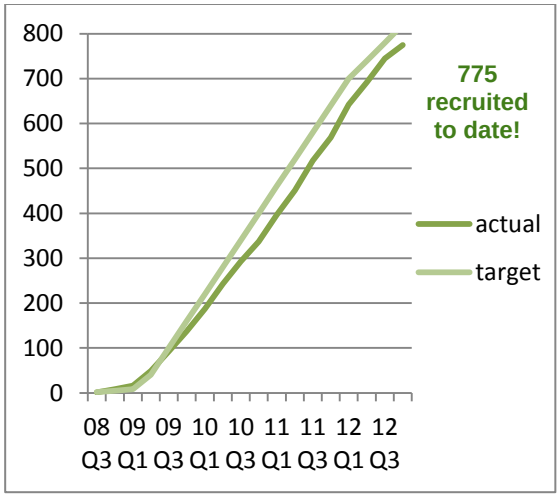
PCR/Biobank samples: Due to postal delays and Christmas closures at the labs the last day for taking/posting bloods for SPIRIT 2 (Hammersmith labs for PCR or Glasgow labs for Biobank samples) is Tuesday 18 December. Samples can be taken/posted again as normal from Tuesday 8 January.

…and January closure day

The Trial Office will also be closed for staff training on Friday 11 January – alternative contact arrangements for urgent queries will be provided nearer the time and will be on our website.

Recruitment – thank you!

We are delighted that recruitment to SPIRIT 2 continues and has now reached 775 patients. This is, as always, due to all the hard work at sites and we are grateful to you all, and to the patients who agree to participate. Recruitment has slowed down in December we would appreicate everyone's efforts to keep it going as we are still a little way off the target.



SPIRIT 2: RECRUITMENT TO DATE

SPIRIT Trials team expands!

We are delighted that we have recently appointed three new Trial Managers to the SPIRIT Trials team increasing our geographical coverage in the South. This has led to some changes in the Trial Manager with responsibility for some sites. If your site is affected you will be told of the new arrangements. A big welcome to Ruth Bescoby, Angela Findley and Carrie Page. They look forward to working with you!

CML Meetings – and a date for your diary

A very successful CML patient conference was held in Glasgow on 17 November. Slides from the day are still being added, but can be accessed via http://www.mpdmeetings.org/. Details of the MPD professionals' meeting which is being held on 1 March 2013 in Newcastle will be posted at the same website shortly.

Home Delivery of study drug

We have had questions from a couple of sites recently asking if home delivery of study drug

is possible within SPIRIT 2. We aware of the benefits and have looked into this, but are sorry to say that this cannot be accommodated within SPIRIT 2. The financial savings to the NHS through SPIRIT 2 are still very large as dasatinib is provided free of charge through the trial. This is a saving of approximately £20,000 per patient per year for 50% of patients on the trial. It is however something we are continuing to review, and are actively considering for future studies.

When is a lab toxicity an Adverse event?

Lab toxicities, where laboratory parameters are outside normal ranges, are not unexpected events when treating patients with TKIs such as imatinib and dasatinib. So how should these be recorded in the eCRF from a trial data point of view?

Patients should have haematology and biochemistry tests (through local labs) at every study visit. The exact tests that are needed are listed in the table in sections 10.1 and 10.2 of the protocol (version 1.4). The eCRF should therefore have data entered for these against each study visit.

All blood test results (whether in relation to a study visit or an interim clinical follow up visit) will be reviewed by a clinician as per normal practice. There will be occasions when results are outside the normal range. Are these adverse events from a SPIRIT 2 point of view? The key questions are whether they are causing any signs/symptoms or whether intervention is required (i.e. are they clinically significant). Clinically significant lab abnormalities are adverse events. See below for further information.

Where these are adverse events, the AE should be entered to the eCRF (recording the worse toxicity grade reached) and data from all blood samples should be entered to the eCRF until the parameter returns to normal range.

Season's Greetings

The SPIRIT Trials team would like to wish everyone a very Merry Christmas and a Happy New Year. Thank you for all your hard work and support for the SPIRIT trials. We look forward to working with you in 2013 and onwards!