



AMBER HINTS, TIPS & UPDATES April 2015

General Update

We now have 6 sites actively recruiting for AMBER and 2 who will start recruiting shortly. As of the 1st April 2015 we have 21 patients recruited into the study, which is an AMAZING start to recruitment. Everyone in the AMBER study office would like to say a **HUGE THANK YOU** to all our sites and everyone in the AMBER team.

We have had some great feedback from all our sites after their first few patients so please read these TIPS and HINTS.

Please get in touch any time you feel you have something to share (positive or negative!!). We hope to start an AMBER research team monthly teleconference in May to make sure all our team at the different sites can share knowledge and be kept up to date!

Sites open to recruiting: The Walton Centre, Preston Royal Hospital, Southern General Hospital (Glasgow), Newcastle Royal Infirmary, St Marys Hospital Leeds and University College London Hospital.

Sites to open April/May: John Radcliffe Hospital, Oxford and Salford Royal.

TIP no 1 – Training DVDs

Please check that the participant has a way of playing the DVD at home. One site had an issue with the DVD not playing on the participant's home DVD player. We have tested the DVDs on various devices and there is no obvious problem however it would be worth mentioning to the participant that if they have problems to call the research nurse to report this. The site research team should get the participants email address and get in touch with the AMBER study office who will email you the link to the video clips. These can then be sent to the participants email.

TIP no 2 – Problems with Randomisation

If there any problems randomising a participant please contact any member of the AMBER team in the Glasgow office and they will be able to help or randomise the patient on your behalf.

Kirsteen Goodman
0141 331 3516

Florence Kyalo
0141 142 9273

Selina Doran
0141 331 8826

If you are going to randomise a participant on a Friday afternoon OR randomise a participant at their home, please get in touch with the AMBER study office before the planned appointment so we can ensure there is someone in the office to carry out the randomisation for you. If there is no one available in the AMBER study office, please contact Tayside Clinical Trials Unit – staff details below.

Cheryl Hume
01382 383898

Margaret Band
01382 383993

Fiona Hogarth
01382 383893

Claire Jones
01382 383923

TIP no 3 – Review of Baseline Bowel Diary

Please review the bowel diary with the participant at their baseline visit. If there any parts not completed please try and go over this with the participant so there is a response for every part of the diary, even if that response is zero or never we want this to be noted. Question 7 (below) on the bowel diary asks about laxative use. Some participants are replying at the side of the question saying they are not on laxatives. Please get the participant to circle USUAL as this would be their “Usual Response” and explain this is how they should complete their weekly bowel diaries. This will help us to have well completed bowel diaries at the end of the 6 weeks.

Laxative use	USUAL**	USUAL	USUAL	USUAL	USUAL	USUAL	USUAL
	MORE	MORE	MORE	MORE	MORE	MORE	MORE
	LESS	LESS	LESS	LESS	LESS	LESS	LESS

In addition, the review of the bowel diary with the participant will give you a good indication to the extent of their bowel problems and also may suggest some useful tips you can give. For example if you see that a patient is spending 30 minutes on the toilet each day, you should advise the patient that this is not good for them and they should only spend 10 minutes using a good posture (as detailed in the MS Society booklet)

TIP no 4 – Study Paperwork

1. The Quality of Life Questionnaire booklet contains 5 different questionnaires, 4 of these are validated. Although each one is designed to capture a different aspect, there will be some repetition across the questionnaires. Please can you make the study participant aware of this at the baseline appointment so they can expect some questions that are either the same or similar to what has already been answered. Please feedback to us in the AMBER study office if this upsets or is an issue for study participants as we would like to monitor this.
2. Part of the Baseline data to complete is the con-med form. All the CRFs required for the study are located in the one CRF booklet. The con med form is located near the end of the booklet on page 30. Please make sure you complete the con-med form as part of the baseline data
3. Patient Follow up packs. Before you give these to patients, please can you make sure you add the study ID to all the paperwork in the packs (6 weekly bowel diaries, patient resource forms and QoL Questionnaire). Make sure the ID is on all pages and not just page 1. This is something that can be done before the baseline visit.

If you have any hints and tips or stories you would like to share on recruitment or any aspect of the AMBER please get in touch with us at AMBER@gcu.ac.uk!