HI-Light Trial Newsletter

Issue 3 Sept 2015

Message from your CI's - Carry on recruiting!

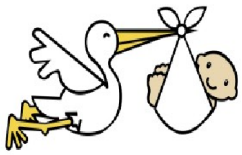
Thanks to all of your hard work, we have got the HI-Light Vitiligo Trial off to a cracking start and are currently on-target with our recruitment figures. I am delighted to say that we received an e-mail from our funders (NIHR HTA) last week to congratulate us on hitting our monthly recruitment targets – so very well done to you all!

However, don't go relaxing just yet. There is still a long way to go. With an ambitious target of 440 participants to be recruited by the end October 2016, there is no room for complacency. Our monthly target is soon going to increase dramatically – so we really need you all to be aiming for 4-5 new recruits per month if at all possible.

I know many of you had concerns when signing up for the HI-Light Vitiligo Trial that it would be difficult to identify participants. Hopefully the incredible response that we have had over the last few months has reassured you that the patients are out there and are really keen to take part. Most centres now have waiting lists of participants, and we are starting to send out approach letters via your local GPs. In our pilot study, we had a 40% response rate from GP approach letters, so we are hopeful that this will provide a good source of participants for the trial.

So good luck over the coming months, and we hope you enjoy being a part of this exciting trial. With very best wishes

Kim and Jonathan

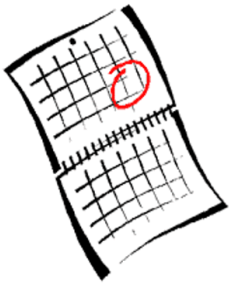


Exciting news … !

Trial Manager Rachel Haines is expecting and will be going on maternity leave in November. Congratulations to Rachel who has done some amazing work in the set up phase of the trial. While Rachel will be sorely missed, the trial must go on…

Meet Garry Meakin!

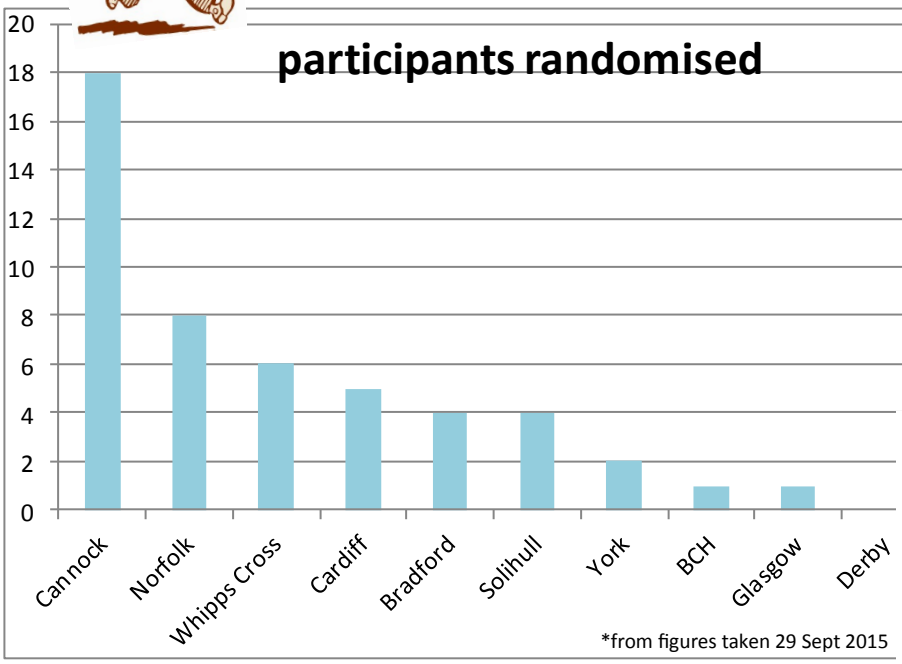
Garry has been working at Nottingham Clinical Trials Unit for just over a year and has recently been promoted from Trial Coordinator to Trial Manager. He has been involved in other trials within the unit including G-ToG (a sexual health trial) and ASAP (a pandemic flu study). Before joining the unit Garry worked as a Clinical Research Scientist. Garry is currently working on setting up new sites and will gradually be phased into the Trial Manager role over the next month.



Monitoring visits

We will soon be back on the road as we begin our initial monitoring visits. Each site will be monitored soon after the randomisation of their 5th participant into the trial. For those sites where this is already the case (Cannock, Norfolk, Whipps Cross and Cardiff) we will be in contact in due course to arrange a visit.

Recruitment—off to a flying start!



Thank you all so much for your terrific efforts, the first few months of recruitment are going really well, as you can see!

Derby are yet to recruit but we have a every faith in them … in fact we think October will be your month!

Month	Participants recruited	Actual
May-15	1	0
Jun-15	3	0
Jul-15	4	9
Aug-15	7	11
Sep-15	10	29
Oct-15	19	
Nov-15	24	
Dec-15	28	
Jan-16	32	
Feb-16	35	
Mar-16	38	
Apr-16	38	
May-16	38	
Jun-16	38	
Jul-16	36	
Aug-16	34	
Sep-16	30	
Oct-16	25	

Whilst we have really excelled with recruitment in this early stage of the trial, the hard work is only just beginning.

As you can see the monthly target will soon start to increase rapidly, with a plateau of 38 recruits per month. This may seem daunting, however we know that with the great team we've got in place this is achievable.

Secret weapons

More sites - we are currently talking to several interested sites and have 6 new hospitals confirmed to take part with their SIVs to be booked over the coming months.

PICs - we knew that PICs would play a huge part in identifying patients for this trial. So far we have done a huge mail out in Cannock (with a 20% response rate so far) and are starting to send out letters in Norfolk, Derby, Birmingham/Solihull and Cardiff. For all other areas we are in touch with your CRN with mail out immanent.

Nurses - things you need to know …

- We have now colour coded the table in which you view existing participants on the randomisation database, hopefully which should make it easier for you to see at-a-glance who needs contacting.
- The 3, 6 and 9 month visits should be calculated using the date of randomisation (not the date you think they have started treatment) with a 2 week window either side.
- As we need to ensure we have good quality images for the primary outcome, we are asking you to check that the photograph for the target patch has been uploaded and is of a good quality just before you call the participants for their 2 week follow up call - in which case you can ask them back should they need their baseline photograph retaking. If this is the case they will receive an additional voucher for the additional trip back to the hospital.
- Head's up for the future: A new substantial amendment with updates to some trial documents has been submitted. We will update your site as to when this has been approved and can be implemented at your site.

Keep in touch

Trial Coordinating Centre;
Nottingham Clinical Trials Unit (NCTU)
Trial Manager - Rachel Haines / Garry Meakin
✉ hilight@nottingham.ac.uk
☎ 0115 8844 938 / 0115 8844 928

Chief Investigator;
Centre of Evidence Based Dermatology (CEBD)
CI- Jonathan Batchelor
✉ Jonathan.Batchelor@nottingham.ac.uk
☎ 0115 84 66947

NOTTINGHAM CLINICAL TRIALS UNIT

Changes that sites MUST implement, *effective immediately*: *ALL PIs, Research nurses and anyone with data collection or data entry responsibilities must return this form, with each bullet point initialled and signed at the bottom, confirming they have taken into account the changes as this update forms part of your trial specific training.*

#	Change	Initials
1	Procedure to record non-related AEs has been updated:	
1a	At EVERY 3, 6 and 9 month visit, participants must be asked the following two questions: *"How has your general health been since we last saw you?* *Have you been admitted to hospital for anything since we last saw you?"*	
1b	Any AEs reported by participants (related or unrelated) must be recorded in the medical notes. Over the course of the trial, the PI must sign off their assessment of relatedness of the AE in the medical notes. Continue recording all related AEs, and all SAEs on the trial AE log, and report to NCTU on the required forms, as necessary	
1c	It is not necessary to record Grade 1 and Grade 2 erythemas in the AE log, as these have been classified as expected treatment effects of the UVB device. This interpretation has been confirmed by the DMC, and clarification of it has been updated in the most recent version of the protocol, which will be circulated to sites upon full approvals. It is however necessary that participants continue to record these in their participant treatment diaries.	
2	Further interpretation guidance of the assessment of the 10% body coverage eligibility criteria has been given by the Chief Investigators, and should be taken into account when assessing potential participants: *'Because of the approximate nature of judging percentage body coverage, an acceptable 'margin of error' in judging the 10% coverage inclusion criteria would be any patient for whom the coverage was felt to be closer to 10% than 20% body coverage'*	
3	There has been an addition of a third response category ('no') for the baseline questions: '*What type of vitiligo is the assessed patch': Hypomelanotic (definitely, maybe, no); Amelantoic (definitely, maybe, no*)'. The data team will shortly raise data queries with sites asking all previously entered responses to this question to be recoded. Sites have 7 days to respond to these data queries.	
4	If the paper data collection worksheets are being used at site, you must ensure the following signatures are present in the worksheet: 1)signature at the end of the enrolment page of the person who took informed consent, 2) signature of the PI on PI eligibility confirmation page, 3) signature of nurse who collected data for that visit at the end of each visit section (Visit 1, Visit 2, Visit 3, Visit 4, Visit 5).	
5	*The above additions to questions or the worksheet will be added to a new version of the data collection worksheets, and updated copies will be sent to sites in due course. However, it is the sites responsibility to make these additions to any previous versions of the worksheets which you may have already used.*	
6	Data from Patient Treatment diaries must be inputted into the eCRF after each Visit (Visit 3, 4 and 5), and not all at once at the end of the study, as previously requested.	

#	Change	Initials
7	Reminder: the pre-screening section of the HI-Light randomisation system must be completed and entered for ALL potential participants. Two updates have been made to this section:	
7a	If a participant reports having heard about the trial from their GP, the nurse must enter the name of the GP surgery into the comments section of the form.	
7b	Reasons for participants not attending a baseline visit appointment after a pre-screen are being expanded to include 1) The participant has declined to participate and 2) The participant lives outside the geographic region of the site. This data should be recorded for all future potential participants who fall under either of these categories, and the trial management team will be in touch with all sites to update the system for any previously screened potential participants who may have fallen under one of these two categories.	
8	Prior to two week phone calls, nurses must check that baseline photographs have been uploaded to the database and are of suitable quality. If the photos are unacceptable, the participant should be invited back for retakes, and an additional £10 voucher offered. Please also flag this up to trial management.	
9	Reminder, the protocol outlines the following response if a participant contacts site after having missed four or more treatments: *"If 4-6 treatments have been missed, the next dose should be around 50% of the last dose given (research nurse will advise participant regarding what dose to administer) If more than 6 treatments are missed, the participants should re-start the treatment schedule from the beginning."*	
10	Changes to side effect log: it is now a requirement that the duration of a side effect be captured on the side effect log (for complete data input into the AE log).	
10a	For participants who have already started using their treatments, when they come back for the 3 month visit, nurses must go through the log and ask for each entry how many days the participant estimates the side effect lasted for.	
10b	For training or retraining going forward, nurses are to tell participants that they must note down the date when the side effect had cleared by in the comments column of the side effect log. *After the next substantial amendment, sites will be issued with new handbooks which will contain an updated version of the side effect log, prompting participants to record the end date.*	
11	The Trial Manual has been updated. Notable changes, which site must take into account are: -anything related to the above changes *(sections 4.3.2, 5.1.2, 5.2, 5.4, 8.2)* -updates to MED section, including procedures and UVB guidance documents from Chief Investigator *(section 5.1.6, Appendix 3, Appendix 4)* - new missed treatments section *(section 7.2)* - new photosensitising medication section *(section 7.3)* - updates to the FAQ section - trial Training checklist *(appendix 2)*	

Name:_____ Signature and Date:_____