HI-Light Trial Newsletter

Issue 1 January 2015

Hello and welcome from our Chief Investigator!

My name is Jonathan Batchelor and I am Consultant Dermatologist at Derby Hospitals NHS Foundation Trust and Honorary Consultant Assistant Professor at the Centre of Evidence-Based Dermatology in Nottingham.

I will be Chief Investigator for the HI-Light Trial, working alongside Professor Kim Thomas.

I first developed an interest in vitiligo when I helped to update the Cochrane Systematic review 'Interventions for Vitiligo' in 2010. My work on the review has given me a fascinating insight into the world of vitiligo trials; there are 96 trials in the current update (which is about to be published). It is fascinating to see such an explosion in the number of trials in the last few years; vitiligo is clearly a hot topic in many countries around the world. However, there is still no ideal treatment for the majority of people who suffer from the condition.

We all know that NB-UVB can be beneficial for some patients with vitiligo. What makes the Hi-Light trial so exciting is the fact that it will be the first to assess home-based NB-UVB for the condition. It will also provide us with a clearer idea of whether combining NB-UVB treatment with topical corticosteroid gives better results than NB-UVB alone. Both of these treatments can be used easily at home, empowering patients to be in control of their own treatment. The trial will also expand the burgeoning evidence base for treatment of vitiligo in its early stages, which may help to slow or stop progression of the disease.

Thank you for supporting the HI-Light Trial. I look forward to working with you all.

Johnathan

Meet the rest of the team! *(left to right; Jonathan, Kim, Rachel, Jen)*

Professor Kim Thomas is Deputy Director of the Centre of Evidence Based Dermatology (CEBD). Her particular interests are in the design and conduct of dermatology clinical trials, and in clinical trial methodology (especially outcomes research), and she has contributed to fourteen independently-funded clinical trials to evaluate interventions for the treatment and prevention of a variety of skin diseases.

Rachel Haines, Trial Manager, has a background in translational research: prior to joining the Nottingham Clinical Trials Unit she worked as a research associate for the Medical Research Council and most recently as an NIHR funded PhD student working in hearing research. Currently Rachel manages three dermatology trials within the trials unit: HI-Light and two paediatric eczema studies, CLOTHES and BEEP.

Jen White, Trial Coordinator, joined Nottingham Clinical Trials Unit as a trial administrator over a year ago. Since then she has been supporting several trials within her team, with particular experience working on dermatology trials including the BEEP and CLOTHES trial, two eczema based studies. Jen has a diverse background, having worked in theatres and charities and brings a creative flare to the team.

Important information for you on the next page - PLEASE READ

A brief update …

- The trial received approval from both REC and the MHRA in November 2014.
- We have 12 sites on board throughout the country.
- We are also collaborating with MRC START (a project funded by the Medical Research Council Methodology Programme) whose aim is to enhance recruitment rates and make research more accessible to the public. We will be filming videos as part of this project in the coming weeks.
- Manufacture of the IMP will be shortly underway, and the first batch of UVB devices are making their way to Nottingham now, for further testing by the Nottingham University Hospitals Trust Medical Physics department … all in preparation for a 1st May 2015 recruitment start!

Important information you need to know

Investigator Training : In addition to site initiation visits, all PIs and Research nurses are required to attend a day-long training session to cover intervention training and patient safety. This session will be run on 2 to 3 dates in March and April to accommodate everyone's schedules. Travel expenses for all attendees will be covered by the research budget. Dates for these events will be circulated in the very near future.

Medical Photography Questionnaires : To help us devise a medical photography procedure that will suit all sites, we have now sent a questionnaire to all of your medical photography departments with a deadline of 23rd January 2015. Could you please get in touch with your medical photography department and make sure they have received it and are happy to fill it out? This is a good opportunity for you to touch base with them before the study starts. If you have not provided us with a contact for medical photography, please do this ASAP.

R&D Approvals : Alongside this newsletter, we are contacting all of your R&D departments with an updated study budget and draft study contract. Site Initiation visits will commence April 2015, with all sites opened for July 2015**.** Please consider internally what timescales you would like to work towards for your site opening.

Recruitment : We want to encourage you to start thinking NOW about recruitment. What you should do:

- Go through your patient lists to identify eligible participants.
- Ask colleagues at hospitals within travelling distance to yours if they would be willing to act as a Participant Identification Centre (PIC) for your site. If so, you would be able to contact their patients with information about the study. You will need to give us the names of the relevant NHS Trusts where PIC activities will take place so that we can gain the appropriate approvals.
- The HI-Light pilot trial very successfully recruited via GP surgeries. Therefore, we will also be using primary care as PICs for this trial, by having GP surgeries in your area send invitation letters out to patients on their lists who have vitiligo yet are not seen in secondary care. We will need to be in touch with your local CRN to organise this process. If you could provide us with the name of who to contact within your CRN to start this process, that would be very helpful.

Identifying potential participants using PICs should not add any burden to your workload. You simply need to provide us with the information requested above, and we will carry forward the approvals process and set-up.

Phone number : Participants will need to be given a phone number for reporting adverse reactions (e.g. erythema) and receiving advice on appropriate treatment modification in such events. This number should be available for participants to call during office hours, Monday to Friday. This may be a number that you already use internally, or we can provide you with a mobile phone from the research budget, if you prefer. Please consider now how you might best organise phone cover at your site. Please let us know the phone number when it has been decided.

Site Staff : Please ensure you have sent us all current CVs and GCP certificates for all members of your site team.

To do list

- ⇒ **Get in touch with your medical photography department and make sure they have received the questionnaire**
- ⇒ **If you have not provided us with a contact for medical photography, please do this ASAP**
- ⇒ **Consider what timescales you would like to work towards for your site opening**
- ⇒ **Go through your patient lists to identify eligible participants**
- ⇒ **Ask colleagues at near-by hospitals if they would be willing to act as a PIC for your site and give us the names of those Trust(s)**
- ⇒ **Provide us with the name of who to contact within your local CRN**
- ⇒ **Please let us know your SAE phone number**
- ⇒ **Ensure you have sent us all current CVs and GCP certificates for all members of your team**

Sites and Principal Investigators

Birmingham - Malobi Ogboli

Bradford - Andrew Wright

Cannock - Seau Tak Cheung

Cardiff - John Ingram

Derby - Jonathan Batchelor

Glasgow - Areti Makrygeorgou

Middlesex - Dev Shah

Norwich - Nick Levell

Nottingham - Jane Ravenscroft

Solihull - Jon Goulding

Whipps Cross - Anthony Bewley

York - Calum Lyon / Julia Stainforth

Something you may find interesting

High prevalence of circulating autoantibodies against thyroid hormones in vitiligo and correlation with clinical and historical parameters of patients.

Colucci R1, Lotti F, Dragoni F et al. Br J Dermatol. 2014 Oct; 171(4): 786-98.

We are all familiar with the fact that around 20% of people with vitiligo have autoantibodies against thyroid peroxidase, thyroglobulin or thyrotropin receptor. This paper takes a step further and assesses the frequency of anti-T3 and anti-T4 autoantibodies in people with vitiligo.

Hoping you and your families had a wonderful Christmas and wishing you all the best for 2015

Keep in touch

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