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Network News

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UK Dermatology Clinical Trials Network

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The LIMIT-1 Study

We are delighted to confirm that funding has been obtained from the NIHR Research for Patient Benefit Programme for the LIMIT-1 study. This 250K award is for an open label, non randomised phase II trial looking at the effect of topical imiquimod in the treatment of lentigo maligna (LM).

The incidence of LM has increased by over 50% in the ten year period from 1993-2003 and is no longer considered a disease of the elderly as the age of onset is decreasing. The current standard treatment for LM in the UK is surgery, which although effective (cure rate of over 90% at 5 years) is stressful and unpleasant, particularly as the head and neck are the most common sites for LM. Imiquimod has significant potential as a first-line treatment for LM for several reasons including the fact that it can be applied by the patient at home, it avoids the cosmetic and functional disabilities arising from radiotherapy or surgery and there are also associated potential significant cost savings to the NHS.

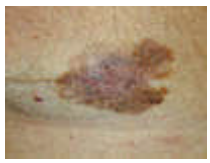


Image of a typical LM lesion

The chief investigator for this study, Dr Jerry Marsden, is based at the Birmingham NHS Foundation trust in Selly Oak. The study will take place at up to eleven recruiting centres across the UK including sites in Birmingham, Cornwall, Southampton, Chesterfield and Lanarkshire. Forty patients will be recruited into the trial and will undergo clinical lesion mapping followed by 12 weeks of treatment with topical imiquimod (with interim visits at 1, 2, 4 and 8 weeks for possible dose adjustment). At the end of this treatment (when the inflammation has subsided) the clinical response will be determined and any new or residual pigmentation mapped. All patients will then progress to biopsy and surgical excision of the area (an apparently healthy margin of tissue will also be taken). The tissue will then be examined histologically to determine the pathological clearance and the presence of LM outside the mapped area.

The primary objective is to establish the pathological complete regression (CR) rate for LM treated with imiquimod. The results of this study will therefore allow recommendations to be made regarding the use of imiquimod for the treatment of LM and inform the need for a further definitive randomised trial. We currently have enough interested centres to complete this phase II study but if you are interested in finding out more and registering your interest to participate in any future related trials please get in touch with the Senior Trials Manager, Jo Chalmers.

UK DCTN Infrastructure Funding Update

We are pleased to announce that contracts for our three part time co-ordinating centre staff (Jo Chalmers, Carron Layfield and Maggie McPhee) have been extended for a further year until April 2010. This has largely been possible due to an underspend on the original grant. Negotiations are continuing with the Department of Health to try and obtain further long-term support for the team who provide a crucial role in co-ordinating and implementing the activities of the Network.

UK DCTN SpR Fellowship Award Winners

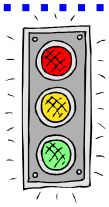
We are delighted to announce the winners of the 2008/9 UK DCTN SpR Fellowship Awards. Launched last year, the aims of the award are to demonstrate the training opportunities that becoming more involved with the Network can offer to the SpR community and to provide the successful applicants with a thorough and complete training in clinical trials research.

The calibre of applicants was again high and the successful applicants were named as Dr Emma Smith, who is currently on rotation in Wales and Dr Fiona Craig who is based in Aberdeen (both pictured below). As part of the Fellowship programme Dr Smith and Dr Craig will now join the UK DCTN Steering Committee and will visit the UK DCTN co-ordinating centre later in the year for further training opportunities They will also attend the BEES dermato-epidemiology course and spend time developing their critical appraisal skills with Prof Hywel Williams.

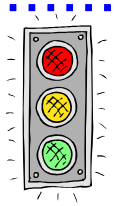
Dr Fiona Craig

Dr Emma Smith

Remember you can sign up for monthly e-mail updates from the NLH Skin Disorders Specialist Library. This will give you links to newly published guidelines, systematic reviews and other resources in the field of dermatology, along with an up to date diary of events. The easiest way to do this is to follow the link on the home page www.library.nhs.uk/skin



Trials in Development Update



Study of trimethoprim for wound healing of patients with epidermolysis bullosa (TREBL)
Following on from the disappointing outcome of the BSF clinical trials award last year this study is now being resubmitted for funding to the HTA Clinical Trials Award scheme. The outline proposal for consideration will be made in April and we expect to know by September whether the study has been considered suitable for full application.

Vitiligo
A research associate has now been employed as part of the CEBD programme grant to co-ordinate the priority setting exercise involved in identifying the most feasible and important study in this area. We will shortly be conducting a survey of clinicians and patients along with some focus group discussions. If you are interested in getting more involved in this workstream then please contact Clare Lushey on 0115 8468633 or clare.lushey@nottingham.ac.uk

Study comparing the use of clobetasol propionate and tacrolimus for the treatment of erosive lichen planus (ELP)
Following on from a presentation of the vignette at the UK DCTN AGM in July, Ruth Murphy is now beginning a Cochrane systematic review of the topic. In addition, funding is being sought for a pilot study to help with the feasibility and design of the main RCT. This will include a retrospective case note review, a survey of centres to assess their willingness to participate in the study and focus group work with ELP patients.

Skin cancer prevention study
Following on from a presentation of the vignette at the UK DCTN AGM in July, Charlotte Proby has submitted a feasibility study to the Chief Scientist Office in Scotland . This study pilot study of 110 patients in Scotland is looking at the field directed cream treatment of actinic kertaoses to prevent keratinocytic skin cancers.

Study investigating the dosage of systemic steroids in the treatment of infantile haemangioma
This study is on hold due to an RCT that is taking place in France investigating the use of propanolol for the treatment of infantile haemangiomas.

On-going Trials Update

With just 12 months left to complete recruitment, we still need a further 135 patients to be randomised into the PATCH I cellulitis study to meet the target of 260. This means that over 11 patients need to be recruited a month from a total of 29 recruiting centres. It doesn't sound like a lot, but only 6 patients were entered into the study in total during October and November 2008 so we really do need to focus efforts on making this study a success and recruiting to target. If you have any ideas on how we can increase recruitment into this study, please contact the PATCH trial manager, Dr Kath Foster. There will be a prize for the best suggestion!!

There are now 35 recruiting centres across the UK signed up for this study investigating the use of doxycycline in the treatment of bullous pemphiogid. Initiation visits are beginning later this month and we hope that the first patient will be recruited by the beginning of February. If you would like more information, please contact the trial manager, Caroline Onions.

There are now 42 recruiting centres across the UK signed up for this study comparing treatments for pyoderma gangrenosum. This is one of the first studies to have gone through the new CSP system of approvals and we hope that the first patient will be recruited by the beginning of April. If you would like more information, please contact the trial manager, Eleanor Mitchell.

If you are a recruiting centre for a UK DCTN study, (or would like to be but don't have the time to get involved) you can get support from your Comprehensive Local Research Network. To date, 17 of the PATCH centres have obtained some form of support (eg a 0.5 FTE nurse) to help with recruitment. If you would like advice on how to do this, please contact Carron Layfield.

Meet a Member: Gemma Minifie
UK DCTN Nursing Prize Award Winner

I am very honoured to have received the UK Dermatology Clinical Trials Network (UK DCTN) Nursing Prize.

I have worked as a clinical research nurse within the field of inflammatory skin disease at the Skin Therapy Research Unit, St. John's Institute of Dermatology for 3 years.

The prize was awarded for my work in the start-up and subsequent daily management of a research investigation into the genetic basis of acne. The project, funded by the British Skin Foundation, is being led by Dr Catherine Smith and Professor Jonathan Barker at the Skin Therapy Research Unit (STRU) at St John's Institute of Dermatology. The primary objective of this research is to recruit a large number of subjects with moderate or severe acne and to identify genes associated with the disease. Understanding the genetic basis for acne will hopefully lead to new therapeutic options for treatment, identify those genetically susceptible to severe (scarring) disease and therefore likely to benefit from early intervention, and determine the relative contribution of environmental factors influencing disease development and severity.

The study is currently in the recruitment phase, collecting samples from St John's Institute of Dermatology and nationally at our partner sites (Glasgow, Harrogate, Leeds, West Hertfordshire and recently Lewisham, Mayday and Orpington). At present we have over 500 patients recruited into the study with our aim being to recruit 3000 patients over the next 2 years.

Recently we have been very fortunate that this study has been adopted by the UK Clinical Research Network (UKCRN). This network supports clinical research across the UK and allows our partner sites to access funding to support recruitment.

I plan to use the nursing prize to build on the theoretical aspects of research I have experienced in practice by attending the BEES 'Getting to grips with evidence-based dermatology' course that runs annually as well as visiting the UK DCTN co-ordinating centre.

New Staff: STOP GAP Trial Administrator and BLISTER Trial Manager

Julie Barnes

I joined the Centre of Evidence Based Dermatology in October 2008 as the STOP GAP trial administrator. Prior to this I worked as a medical secretary in the busy Dermatology Department at QMC in Nottingham for 5 years, and as a medical secretary in the psychiatric services for 7 years before that. If you are a STOP GAP investigator and need any help or information, please contact me on 0115 8230486 or j.barnes@nottingham.ac.uk

Caroline Onions

After completing my degree in Medical Science I won a place on the NHS Management Training Scheme and started working as a manager in the health service. After 5 years of working in the NHS in Manchester and London, I decided that a career in clinical trials would be a great way to combine my academic science background with the management skills I had from my time in the NHS. Prior to my current role, I managed a large multi-centre trial in Alzheimer's disease through set up and recruitment.

I joined the UK DCTN in October 2008 as the trial manager for the BLISTER trial, a study looking at treatments for bullous pemphigoid. If you would like to find out more about BLISTER or need to get in touch with me, I can be contacted on 0115 8230510 or caroline.onions@nottingham.ac.uk

Julie Barnes
STOP GAP Administrator

Caroline Onions
BLISTER Trial Manager

UKCRN Training Reminder

Please do remember that as a member of the UK DCTN you are entitled to attend all UKCRN training courses free of charge. A full list of courses can be found on www.ukcrn.org.uk/index/training.html and both basic and advanced topics are covered, along with courses for consumers and specific areas such as recruiting into paediatric studies. The courses are held at venues across the country and a number, eg GCP are available to study on-line. For further details please contact Carron Layfield.

Dates for your Diary

Thurs 14th May	Annual Evidence Based Update Meeting (Urticaria)	9.30am	Holywell Park Loughborough
Thurs 9th July	AGM and Steering Committee Meeting	5pm	BAD Annual Meeting, SCC Glasgow
Fri 10th July	Executive Committee Meeting	8.30am	BAD Annual Meeting, SCC Glasgow

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