UK DCTN AGM & Steering Group Meeting Minutes

BAD Annual Meeting, Manchester Central Convention Centre

Tues 2 July 2024 11.30-1pm

Attendees: Beth Stuart (Chair), Nick Levell, Tim Burton, Carron Layfield, Evelyn Davies, Maggie McPhee, Hywel Williams, Rachel Abbott, Abby Macbeth, Andrew Pink, Shernaz Walton, Zenas Yiu, John Ingram, Debbie Shipley, Jo Searle, May Havinden-Williams, Laura Davey, Esther Burden-Teh, Khalyen Mistry, Gemma Whicker, Grace Boyd, Alison Sears, Hannah Wainman, Becky Dingle.

Online: Jane Sterling Fiona Cowdell, Areti Makrygeorgou, Lucy Bradshaw, Tracey Sach, Anna Lalonde, Mark Aldred, Simi Sudhakaran, Alia Ahmed, Alison Layton.

Apologies: Kim Thomas

Actions

	Action/ Resolution	*Owner*	*Date due*
	Psoriasis Vignette – Feedback from today to be forwarded to author – P Hampton	Margaret McPhee	11 July 2024

Minutes

1. Welcome

Beth Stuart welcomed everyone to the meeting and reminded those present to sign in so the numbers attending can be recorded for this AGM.

For those not already aware, Beth introduced the UK DCTN deputies – Consultant Dermatologists Eveyln Davies and Zenas Yiu, appointed last year to support Beth in her role as Chair.

Beth offered many congratulations to Prof Nick Levell, a longstanding supporter and Executive Committee member of the Network who has been awarded an MBE honours and also Dermatologist of the Year award from the BAD.

2. Minutes of previous meeting and matters arising

The actions from the previous minutes (paper 1) were completed:

- THESEUS (HS) – feedback to study team
- OPINION (Vitiligo) – feedback to study team
- SPOT-IT (cSCC) – feedback to study team
- Help with recruiting if you can - TIGER, Dexacell, RAPID, SCC-AFTER

No further comments on the previous minutes which were accepted as a true record.

3. AGM Business and Treasurers report

Nomination of new Steering Committee members:

- Hannah Wainman – nominated by Beth Stuart, seconded by Hywel Williams
- Maanasa Polubothu – nominated by Beth Stuart, seconded by Shernaz Walton.

Treasurers report (paper 2)
Carron Layfield presented the Treasures report for the charity finances. This does not include staffing costs or any funded studies. These funds are principally gained from contributions from funded studies. They pay for training, awards and fellowships, and additional costs such as the exhibition giveaways and trustee insurance. Carron explained the refunds which were to studies withdrawn or finished.

Total Account balance: £115,703.87
Committed funds for 2024/2025: £48,503.68
Total funds available: £67,200.19

Accounts formally approved.

Honorary Lifetime membership awards:

Beth Stuart presented Debbie Shipley (Consultant Dermatologist Bristol) with our honorary UK DCTN lifetime membership award.

An award was also made to Amanda Roberts, a patient representative and Co-Lead on the RAPID eczema study, but she was unable to attend this meeting.

4. New Vignette - Management of Chronic Plaque Psoriasis – (study lead Phil Hampton) presented by Zenas Yiu

This study proposal is in response to a re-advertised NIHR HTA Commissioned Call on Management of Chronic Plaque Psoriasis.

The study is a randomised observer blind trial comparing methotrexate sc injection with adalimumab in patients with moderate psoriasis with PASI scores ≥5 and <10.


MethorMab
vignette presentatio

Aims: To compare PASI 75 outcomes at 16 weeks in patients receiving adalimumab and methotrexate with starting PASI scores of ≥5 and <10 and to conduct an economic evaluation to estimate the cost-effectiveness of adalimumab compared with methotrexate, with work done to extrapolate costings beyond the 24 week end of trial to illustrate costs over 5 to 10 years of on-going treatment.

Justifications for study:
- According to current criteria psoriasis patients with PASI score under 10 do not receive biologics medication (prescribed systemics and topicals) but are highly likely to be an effective treatment for this group of patients.
- Methotrexate causes several side effects for many patients but Adalimumab might be more tolerable for them with less side effects
- New biosimilars are reducing in price so adalimumab could be a more cost-effective treatment.

Intervention: Adalimumab sc injection 40mg 2 weekly
Comparator: Methotrexate 17.5mg sc injection weekly

Inclusion criteria:
1. Aged 18 or over with PASI score of 5 or over and < 10
2. Willing to use a self-injection therapy

Exclusion criteria:
1. Severe psoriasis with PASI 10 or over, mild psoriasis with PASI less than 5.
2. Aged under 18
3. Had treatment with methotrexate or adalimumab within 6 months of recruitment.
4. Unsuitable for treatment with MTX or ADA for any reason.

This two arm study over 24 weeks will include blood tests at 4 weeks, then measure PASI and DLQI scores at week 16.

Secondary outcomes, EQ-5D and Healthcare utilisation to be measured at week 24, end of study.

Discussion points:
- TB - Methotrexate and adalimumab are very different medications- have patients provided an input in the design of this study? Many might not want to take methotrexate because of the side effects.
- TB - Considered burden to patients? Might not be an attractive option to patients so either would not join the study or drop out.
- BS - Important to have patient input on the design of this study. (Patient issues have been raised in earlier feedback).
- BS - Be clear whether this is a superiority trial or non-inferiority trial. This can affect the sample size required. Also need to be precise for the HTA panel.
- ZY - Observational data obtained from BADBIR shows possible superiority so need to make this clear.
- NL - Patients tend not to like methotrexate. Patient experience important to consider and include.
- HW - Need to make a good case for this research questions which currently is not quite convincing enough
- HW – Lack of equipoise – need to emphasise why patients would recruit to this study
- HW - could discuss with NICE, by consulting with them, they might support the need for the study i.e. gap in the guidelines
- HW - Look at the required monitoring in more detail. Are blood tests needed? (There is some evidence out there that they are not needed for methotrexate)
- HW – suggested some qualitative work on patient views and experiences re the medications and the condition (moderate psoriasis)
- HW - Look at dosing strategies - do they match usual care?
- HW – Consider other outcome measures? Further stats needed?
- Conduct a survey to clinicians asking about their usual practise?
- TS – Cost effective evaluation for the trial – need a better case for doing this study.
- Possible that secondary care don't see enough 'moderate' psoriasis patients so may need to recruit from Primary Care too?
- Conduct pilot /feasibility study to identify how many patients could potentially benefit from this study. Or a survey to clinicians between stage 1 and 2.
- District general hospitals might recruit
- Patient criteria – add patients that have not used the drugs before
- Consider diversity of patients – recruit from many different areas with different populations. Is PASI best to use for darker skin tones? Check this.
- If using continuous measures, will need a smaller sample size.
- How can we diversify and find patients under treated or not prescribed these meds before?
- TB – PPI input - Ask patients who may have experience of both study drugs
- Threshold on DLQI measure? A low PASI might still be a high impact for patients.
- Patients might not be able to continue on the drug (due to NICE guidelines) if on biologic arm at end of the study. Ensure this is mitigated for.

Action: Feedback from today to be sent to authors.

5. Identifying Priorities for future NIHR HTA commissioned calls

The HTA have made contact with the UK DCTN collect research priorities to submit to the NIHR HTA team for commissioning dermatology trials. We have been collating your ideas and forwarding on to the HTA team. They will then contact you if they are interested in discussing your proposal/research priority. The plan is to eventually release a HTA commissioned call (open competition) to fund research on your proposed topic/idea.

The form to submit your research questions can be found here:
https://forms.office.com/e/CGTDFJ4X71

Video from Eve Pearce, Research Manager, NIHR describing funding opportunities from the Health Technology Assessment (HTA) with guidance on how to make a successful application:
https://mediaspace.nottingham.ac.uk/media/Guidance+on+NIHR+HTA+Commissioned+calls+-+Eve+Pearce/1_afqjlx68

In summary, the HTA is 30 years old and provides big budget funding to clinical trials. This includes systematic reviews, RCTs, screenings, cohort studies and adaptive designs. They do NOT fund epidemiology work, phase 2 trials or new equipment. There are two workstreams i. Researcher-led and ii. Commissioned calls (specific topics) But they do forward proposals to other funding bodies if an application is not suitable for HTA funding.

A PICO form/ template is provided to ensure all questions are answered fully (you can request this from us or HTA). Central issue is to ensure your question is interesting and useful to both health professionals and patients.

6. Trial Generation and Prioritisation Panel (TGPP) Update

TGPP Chair Rachel Abbott provided an update of the activities of the panel.

Membership -two new members joined – Andrew Pink (GSTT) and Jaskiran Azad.

UK DCTN Trainee Groups 2024 – One day course completed and now have four groups currently designing a study. This is for educational purposes, but some groups have persevered to a full trial eg HEALS2 and EXCISE.

UK DCTN Themed Call Award (Completed Priority Setting partnerships) – Three awards available, closing: 22 July 2024. http://www.ukdctn.org/funding-awards/ukdctn-funding-awards.aspx

UK DCTN Fellowship Awards – closing: 7 October 2024 Open to SpRs, Nurses, GPs and SAS. Please apply.

7. Study updates

Carron Layfield provided update of all current developing and ongoing studies.

Current studies (recruiting participants) that need help from membership if possible:

- TIGER eczema study –Can dietary advice based on food allergy tests improve disease control in children under 2 years with eczema - need help recruiting from primary care. See https://tiger.blogs.bristol.ac.uk/ for details
- COAT cellulitis - recruiting from primary care and now from Emergency departments

- BEACON (adult eczema study) – comparing ciclosporin, methotrexate and dupilumab. Need more recruiting sites. If interested please email BEACON@kcl.ac.uk Also there is an option for eczema patients to self-refer via the website https://www.beacontrial.org/
- RAPID – creating studies with patients answering questions they want answered _ 'citizen science/ co-production approach. First study looking at frequency of bathing now recruited to target. Future studies include: keeping control of flares, managing stress (psychological interventions)
- PEARLS – Proactive versus reactive therapy for the prevention of lichen sclerosus. Five sites now open and additional 15+ sites opening across UK next few months. Email PEARLS@nottingham.ac.uk Managed by Nottingham CTU.
- HEALS2 – Compression and healing of excisional wounds on lower legs by secondary intention Pragmatic RCT evaluating the clinical and cost effectiveness of compression therapy in the healing of surgical wounds (healing by secondary intention) following excision of lower limb keratinocyte cancers. Will recruit 396 participants from secondary care skin cancer surgical centres. There are 12 centres opened to recruitment.– opening 22 sites in total across UK with more sites needed https://ctru.leeds.ac.uk/heals2/

Studies in set-up:

- SCC-AFTER - Adjuvant radiotherapy for high-risk SCC This study will look at whether adding in a course of radiotherapy following surgery in 'high-risk' squamous cell carcinoma patients will help prevent local recurrence.
- ACNE-ID - Benefits and harms of reduced dose isotretinoin for acne - this study will compare two different dosing strategies and aims to recruit 800 patients from 20 sites. Email: acne-id@nottingham.ac.uk if you want to become a recruiting site.

Newly funded studies:

- SPOT-IT - SCC prevention using topical therapy in immunosuppressed and immunocompetent patients.
- Dexacell - Dexamethasone for cellulitis.

Studies in development:

- OPINION (vitiligo) study Unfortunately funding application not successful. Team to re-visit proposal.
- THESEUS – Hidradenitis Suppurativa – outline funding application submitted to NIHR HTA

8. AOB

Reminder of BAD conference plenary session - Professor Beth Stuart to talk at 9am 4 July "Clinical Trials in dermatology - Lessons Learned and thoughts for future designs"

Exhibition hall – UK DCTN at stand at PSG2 for duration of conference

Dates of next Steering Committee meeting:

1.30pm Tues 8 October 2024 Online (Themed Call award applications)