UK DCTN AGM & Steering Group Meeting Minutes

BAD/ Online

Tues 27th June 2023 11.30-1pm

Attendees: Nick Levell (Chair), Fiona Cowdell, Tim Burton, Carron Layfield, Evelyn Davies, Laura Howells, Jane Sterling, Maggie McPhee, William Price, Rachel Abbott, Abby Macbeth, Helen Young, Amanda Roberts, Andrew Finlay, Alia Ahmed, Kyle Tang, Andrew Pink, Sinead Langan, Alison Sears, Jaskiran Azad, Shernaz Walton.

Online: Areti Makrygeorgou, Satveer Mahil, Catherine Smith, Tim Burton, Lucy Bradshaw, Tracey Sach, William Price, Shyamal Wahie, Fiona Cowdell, Mark Aldred.

Apologies: Louisa May Adams, Anna Lalonde, Charlotte Gollins, John Frewen, Mel Westmoreland, Rubeta Matin, Sarah Worboys.

Actions

	Action/ Resolution	*Owner*	*Date due*
	Vignette 1 – Feedback from today to be forwarded to authors	L Howells	July
	Vignette 2 - feedback from today to be forwarded to authors (but funding application deadline in August) Include survey in next UK DCTN email update	L Howells M McPhee	July 6 July
	Publicity for BEACON study	C Layfield	As needed
	TGPP vacancies – please contact M McPhee if interested	All	

Minutes

1. Welcome

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

N Levell updated everyone on the vacancy of Chairperson for the UK DCTN, now that H Williams is approaching retirement. This post was re-advertised to allow non-clinical applicants to apply. Applications have closed and interviews are scheduled to take place on 4 July.

2. Minutes of previous meeting and matters arising

The minutes

- Feedback sent to Dr Philip Hampton (PG study) and survey circulated to clinicians.
- Feedback sent to Dr Stephen Smith (non-melanoma study).
- SPOT-IT study submitted for funding by Dr Catherine Harwood.

3. Treasurers report (paper 1)

C 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 Survey Monkey account and Zoom meetings for the trainee journal club.

Total Account balance: £112,947.83
Committed funds for 2023/2024: £72,690.23. Additional funds required on making the Chair role a funded post (£10k).
Total funds available: £49,257.20

Accounts formally approved (Sinead Langan/ Kyle Tang).

Lifetime Membership Awards

N Levell presented an Honorary Life Membership Award to Professor Andrew Finlay in acknowledgement of his work for the Network. Andrew Finlay was involved in the Network from the very beginning and served as Chair of the Executive committee for several years. A Finlay thanked the UK DCTN for this recognition, commenting he enjoyed his time with the Network and supports its ethos today.

An honorary lifetime members certificate was also awarded to Dr Alison Layton but she was unable to attend this meeting.

4. Main agenda items

4a. New Vignette 1 – Does use of topical oestrogen reduce symptoms and improve quality of life in adult women with vulval lichen sclerosus when compared with placebo over a 3-month period?

Presentation by Jaskiran Azad:

This proposal is for a multi-centre feasibility study looking at vulval lichen sclerosus (LS). Originally submitted for the themed call award (not successful but significantly re-designed after input from H Williams and L Howells).
Dr J Azad demonstrated there were evidence gaps on the effectiveness of treating LS with topical oestrogen, so more research needed. This topic was selected as a research priority by the JLA Priority Setting Partnership – 'Are there effective topical treatments other than topical steroids in the treatment of lichen sclerosus?'

After consulting with PPI groups, they seemed to favour the oestrogen vs placebo study design, however based on feedback from clinicians and the UKDCTN TGPP, the revised research question presented for an RCT was: Does addition of topical oestrogen to standard topical corticosteroids (TCS) reduces flares and improves quality of life in adult women with VLS at 6-month follow-up?
Inclusion: Patients with clinical diagnosis of VLS and with active disease above 18 and able to use pessaries per vagina after clinical assessment.

Exclusion: history of breast or endometrial cancer, deep vein or pulmonary thrombosis, allergy to oestrogen products, PMB, premalignant or malignant changes.

Tools: Severity of vulvovaginal symptoms measure (VuAS), Vulvar disease Quality of Life index (VQLI), and diaries.

Feasibility study research question: Is it acceptable and feasible to conduct a RCT to compare effectiveness of topical oestrogen in addition to standard TCS treatment for VLS relative to TCS treatment alone?

Plan to recruit 40 patients for feasibility study from 3 sites over 6 months.

Primary objectives:

- To determine how many people accept the invitation to participate in the study.
- To explore how many patients with VLS are eligible to recruit
- How many women agree to enter trial period and agree to randomise
- To measure percentage of participants who are able to self-report data for assessments, assessment completion rates by research nurses, missing data, estimates, variances.
- To collect and synthesize data to inform the sample size estimation for a subsequent RCT.
- To inform the RCT of time scales required and therefore more accurate assessment of costs.

Discussion points:

- Will it be possible to provide the topical oestrogen and TCS as a combined treatment to reduce treatment burden? Jaskiran explained that this was not possible due to the blinding of the study (i.e. both groups needed to receive identical looking treatment for oestrogen or oestrogen placebo. They found a pessary would be preferred in PPI work, but the pharmacy costs for a specifically made placebo pessary would be around £80k for the full RCT. Discussed how burden of treatment and how people found using pessaries could be issues explored in the feasibility work.
- Appropriate sample size for main study? Screen 100 patients.
- There was a concern that this study design may miss the opportunity to look for steroid sparing effects and it there was a suggestion to add oestrogen alone arm. A three arm study was considered and presented at a previous UK DCTN meeting, but the concerns from that meeting that what was presented was a complicated study design. There are also concerns about cost.
- Oestrogen not an anti-inflammatory, can you ensure that you are measuring changes in LS and not other non-LS related symptoms? Think it will be important to include young women in study, and even children were discussed too (but a challenge is that oestrogen is only licensed for post-menopausal women)
- Due to media interest, more menopausal-aged women on oestrogen these days, and so it might prove harder to find women who are not already taking oestrogen. This is why the feasibility work is important.
- Some older women (post-menopausal) might find pessary difficult/ uncomfortable. Discussed how need to choose one for blinding purpose. Exploring option of syringe application too, but waiting for the costings of that yet.
- For the outcome measures selected, is it known in the literature what is a clinically significant improvement in scores / minimally important change? No use in being able to show a statistically significant difference if that difference is not also clinically meaningful / meaningful to patients. E.g. If trial shows a two point difference is scores between the groups, do we know if women find a 2 point change meaningful? If this work is not available in the literature, could consider doing this work within or alongside the feasibility study to ensure RCT results will be interpretable.
- It was recognised that lots of the patients involved in PPI word did not have LS, and going forward it would be good to involve more patients with experience of LS to strengthen PPI involvement. Suggestion to tap into support groups.
- Placebo effects were discussed.
- Questioned if the treatment period of 12 weeks would be long enough? It was clarified that the main trial will be for 6 months at least, and feasibility work does not include treatments.
- Suggestion to invite nurse to join study team.
- Summarised that it was an important clinical question that has support of UK DCTN.

Action: Feedback from today to be sent to authors.

4b. New Vignette 2 – Can we use 'as needed' biologic treatment to sustain disease control and reduce healthcare costs in people with psoriasis?

Presentation by Satveer Mahil:
This study is in design to apply for NIHR HTA funding in response to a commissioned Call on Management of Chronic Plaque Psoriasis (deadline August 2023).
The rising prevalence of psoriasis and routine use of newer generation highly effective biologics (IL-23 inhibitors and IL-17 inhibitors) has led to increasing numbers of patients with well controlled disease, who are continuing treatment indefinitely, despite limited evidence this is needed. This study will look at applying 'as needed' treatment regime rather than regular appointments. If effective this could bring significant savings to the NHS and reduce side effects. This addresses the patients question – "Do I need regular biologic injections for the rest of my life"

- This study has ongoing input from a clinical focus group and patient support group (via the Psoriasis Association).
- Only those with severe disease can access biologics. If needed less regularly this could open the treatment to more patients.
- PsoProtect Me registry data showed that 25% patients paused or stopped their treatment during the pandemic.
- If skin is clear or nearly clear then the next dose would be at the next sign of severe psoriasis rather than continuous.
- Some patient views – 'I know when I need my next injection'
- Fits with NHS England guidance to personalise treatment.
- Some patients remain clear for up to six months after withdrawal of biologic.
- Literature shows re-treatment can re-establish control quite well.
- Aligns with HTA - can it sustain disease control and reduce costs?
- Inclusion – Psoriasis patients clear or newly clear on biologics already
- Aim to recruit 342 patients 171 in each arm. Biologic injection on recurrence compared to standard care of fixed dose intervals over 18 months.
- Patient reported outcomes via My Skin Platform
- There will be a feasibility study that will be completed before this study to assess barriers to recruitment.
- Inferiority study design
- Clinician survey open now:

https://forms.office.com/Pages/ResponsePage.aspx?id=FM9wg_MWFky4PHJAcWVDVldkFS5Tt5tDt6lgNXisraZUMTRCT1U2UTdHWUZHNkQxOUlQOE9IVURCSy4u

Discussion points:

- Will there be a minimum and maximum duration for the 'gap' between injections? It was explained that there will be close monitoring via the online platform, and instructions will ensure that they do not take more frequently than appropriate.
- Patient view was expressed that some people may concerned that their treatment will not work so well if they stop and restart. This has happened with some treatments in their experience. Potential problem if treatment stops working after re-starting it, so important to inform patients of this risk. It was explained that it is not anticipated that this study will be for all patients, it is about finding a solution for a sub-group of patients that it may be the right choice for. It was also explained that this tends to happen in first six months of new treatment. Patients recruited will be those who are well established on the treatment. There is also the option to change to a different biologic if it stops working for the patient. But was agreed patients need to be informed about potential risks.
- Rigid prescription guidance for biologics – how to get around that? Consulted with pharmacist. Aim to provide 3 months supply to patients so they have access when they need it.
- Important to use core outcome set for psoriasis
- Question about how reoccurrence will be defined. It will be self-defined by patient. Concern that this might differ between patients (e.g. some will wait until it is a certain 'level' before they feel it counts as a recurrence). There will be instructions to help clarify what is a recurrence that should be acted upon.

- Use of patient global assessment scale discussed.
- Use of photographs to show reoccurrence discussed (but also concern patients might not want to upload photos).
- It was questioned if there would be a 'reloading' dose vs maintenance dose.
- Suggested there is a mismatch between PASI and DLQI scores, so PASI should be conducted by clinicians to make study more robust.
- PIFU not suitable for all patients, so the it was felt that the option to be seen in clinic should be added. Reducing follow up for patients may reduce 'safety net' for some patients.
- Expiry dates of drugs should be logged and noted to ensure patients always have an injection they can use when a recurrence does occur.
- It was discussed as important to have pharmacist involvement in the study team. There is already a pharmacist involved, but pharmacist present at the meeting also was keen to hear about how to get involved.
- Expressed a concern that some patients may take their treatment towards the end of the study, even if they do not require it, due to concerns that they will be taken off the treatment/lose access to it if they have not needed it during the study.

All present were in support of this study.

Action: Summarise and return feedback from this meeting to author

5. BEACON Study Update (Best systemic treatments for adults with atopic eczema over the long term)

Andrew Pink reported on the progress of this study. Acknowledged it has taken time to get the design right. They will be comparing active treatments (not placebo as most biologics trials for eczema have been to date).
The main aim of the study is to determine the effectiveness, tolerability and cost-effectiveness of methotrexate and dupilumab compared to ciclosporin, in adults with moderate to severe atopic eczema.

Aim to recruit 402 patients (see slides attached). Patients will be able to self-refer to join study.

Inclusion criteria: Adults, diagnosis of atopic eczema, moderate to severe disease requiring systemic therapy (vIGA-AD ≥3 at baseline).

There are drug specific exclusions for ciclosporin, methotrexate and dupilumab.

It has been submitted to the MHRA/REC for review. It is hoped to begin recruitment within the year, but this is dependent on the outcome of the MHRA review.

This will be a platform 'living' trial to incorporate new drugs. First planned addition to the platform is abrocitinib (contract signed with Pfizer).

Proposed long-term follow-up through A-STAR – data sharing agreement etc in development.

Trial Manager – Sam Curtis, email: BEACON@kcl.ac.uk

Discussion:

- C Layfield offered continued publicity via the Network to help with recruitment sites and recruiting patients. N Levell offered to email sites via NIHR role.
- Discussed the need for a statistical data monitoring committee i.e. changes to the 'living' platform trial.

- Questioned what will happen if patients are not eligible for the treatment they are on after the trial? (e.g. for dupilumab). This will need to be included in the participant information sheet.

6. TGPP Update

Rachel Abbott provided update of the activities of the panel.

Skin of Colour Themed Call - Two10K awards available (co-funded with NES) Deadline: 17th July 2023 so still time to apply.

2024 themed call will be 'Supporting recently completed PSPs'

Trainee Groups 2024 – This is in the planning stages. Mentors appointed to support the groups. Open to applications later this year.

Vacancies on the Panel - More panel members needed to help review the vignettes (research proposals) when they are first submitted. Contact Maggie McPhee if interested.

7. Awards and Initiatives

UK DCTN Themed Call Award – Skin of Colour, closing 17 July

UK DCTN Fellowship Awards - closing date 23 October 2023

UK DCTN Trainee Groups 2024

8. AOB

None

Dates of next meetings:

1.30pm Tues 17 October 2023 Online (Themed Call presentations)

1.30pm Tues 6 February 2024 (BAD, London)

The UK DCTN is grateful to the BAD for their on-going support, particularly with regards to funding towards co-ordinating centre staff. To find out more about the Network, please contact carron.layfield@nottingham.ac.uk or visit the website www.ukdctn.org **Nick Levell (Interim Chair) and Carron Layfield (Network Manager)**

UK DCTN Annual Treasurers Report
(01/04/22-31/03/2023)

Income 2022-2023		
BEACON		£10,000
TIGER		£5,000
ACO		£2,000
Satveer Fellowship		£6,000
Account interest	£684.26	
Total income		**£23,684.26**
Spend 2020-2021		
UK DCTN Fellowships	£6988.72	
2019 Themed Call (Derm Surgery PSP)	£8127.12	
2021 Themed Call (Eczema Telederm)		£1658.65
Trustee insurance	£338.67	
Zoom (Online journal club)		£100.73
Fees		£204
Honorariums		£250
Survey monkey		£384
AGM catering		£375.60
Giveaways		£631.62
Misc committee travel		£82.80
Total spend		**£19,141.91**
Account Balance		
Current Account Balance	£5,991.87	
Deposit Account Balance	£106,955.56	
Total Account Balance		**£112,947.43**
Committed funds 2023-2024		
UK DCTN Fellowships (x5)		£8,750
2019 Themed Research Call (Derm Surgery PSP, dissemination)		£1,772.88
2021 Themed Research Call (Acne)	£9,961	
2021 Themed Research Call (Eczema Telederm)		£8,121.35
2022 Themed Research Call (Genital)		£10,000
2023 Themed Research Call (Skin of Colour)		£10,000
2024 Themed Research Call (Supporting PSPs)		£10,000
2023-2024 UK DCTN Chair Costs	£10,000	
Trustee insurance		£350
Zoom		£150
Survey monkey		£385
Fees		£200
Office running costs		£3,000
Total Committed Funds		**£72,690.23**
Total funds available 2023-2024	**£ 40,257.20**	

Please note these figures refer solely to our bank accounts and are not related to grant funding which supports the UK DCTN on-going studies or donations from BAD towards UK DCTN salary costs.