Summary of pyoderma gangrenosum feasibility study

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Summary
The UK Dermatology Clinical Trials Network (UK DCTN), in collaboration with The Centre for Healthcare Randomised Trials (ChaRT) (Health Services Research Unit at the University of Aberdeen) has developed a protocol for the first randomised controlled trial (RCT) to compare commonly used treatments for pyoderma gangrenosum. This will assess, head-to-head, the most widely used topical and systemic interventions in a disease that is relatively rare, but which has severe consequences for patients and represents a relatively large drain on NHS resources.

This study is designed to assess the feasibility of conducting the future RCT. In particular, it will inform the design of the RCT; assess the viability of using digital images taken by the participants to capture time to healing for the study; assess the willingness of clinicians to randomise patients into the study; and involve patients and their carers in the research process at an early stage.

This work comprises three separate pilot studies:

The first pilot study is a retrospective case note review that will be used to assess incidence, therapy, morbidity, co-morbidity and time to healing. This aspect of the study will be used to inform the recruitment strategy by assessing the suitability of eligibility criteria, providing data to inform sample size calculations and estimating the number of patients who are likely to enter the topical and the systemic arms of the trial.

The second pilot study will assess the use of digital photography to capture the primary outcomes of time to healing and velocity of healing. Importantly, the study will explore the novel use of digital images as taken by participants themselves.

The third pilot study will employ qualitative techniques (focus groups, structured interviews, research meetings and surveys) to capture the opinions of patients with pyoderma gangrenosum, clinicians and the public, in order to ensure that the trial addresses their concerns and to get advice on design, focus and ethics of the RCT. This aspect of the study includes a survey of the membership of the UK Dermatology Clinical Trials Network and a survey of members of the European Dermato-Epidemiology Network (EDEN) in order to assess the willingness of European colleagues to take part in the proposed RCT.

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