

Research Letter – Research Priorities in the Management of Hidradenitis Suppurativa.

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Research Letter – Research Priorities in the Management of Hidradenitis Suppurativa.

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Dear Editor

There is a need for high quality research evidence to support the management of hidradenitis suppurativa (HS) (1, 2).

The *Treatment of Hidradenitis Suppurativa Evaluation Study* (THESEUS) seeks to contribute to this by informing “the design of future HS Randomised Controlled Trials (RCTs)” (3). Its objectives include characterising potential study interventions, determining current patient pathways, contributing to the validation of a core outcome set (4), and establishing the feasibility of future trial recruitment (3). In this article we provide a report of one aspect of its work – a consensus meeting to prioritise future RCT designs.

In June 2022 a hybrid consensus meeting was hosted by the THESEUS team. Thirty individuals participated, including 7 healthcare professionals (primarily THESEUS local principal investigators), 10 researchers, and 13 people living with HS (advocates for HS groups or THESEUS participants). Fourteen of these joined online via the zoom platform (including 7 people with HS).

A list of possible HS treatment comparisons was the focus of the meeting. These comparisons were identified by the THESEUS Study Management Group, including interventions used in THESEUS as well as others that are commonly used. Selection was informed by clinical guidelines and prioritised interventions unlikely to be investigated by the pharmaceutical industry.

The meeting took place in a single day and followed the nominal group technique (5). Prior to the meeting participants were asked, via an online form, to identify up to three treatment comparisons where future research would be valued. During the meeting, small group and whole group discussion (followed by scoring) identified a smaller number of *preferred trials* before finalising a set of *priority trials*.

Figure 1 shows the transition from twelve trials to three *prioritised* trials.

It is of note that Option F (“Early intervention usually used later in treatment in care pathway (e.g biologics) compared to doxycycline”) was considered to generically capture the specifics of other options, so despite an agreement about its importance it was not carried forward. Early intervention to prevent longer term consequences was thought an important goal for future HS research.

Early discussion also led to Options C (Laser versus clindamycin and rifampicin) and D (Clindamycin and rifampicin + laser compared to clindamycin and rifampicin alone) being merged to a new Option M: “*clindamycin & rifampicin + laser v. laser alone*”.

Four options were *preferred* following discussion, Options K (Adalimumab + laser compared to Adalimumab alone), E (Deroofing of skin tunnels compared to local excision surgery), L (Adalimumab + deroofing compared to Adalimumab alone) and Option M.

In the final scoring three *prioritised* options were identified: Option K gained 25 votes (50% of the votes cast), M 16 votes (32%) and E 8 votes (16%); Option L received only 1 vote (2%). All bar two individuals living with HS selected Option K, 75% of votes for Option E (6/8) were from individuals living with HS.

Discussion suggested that increasing access to treatments that are not commonly available in the UK was a factor in prioritising deroofing, laser hair removal and biologics. Alongside this, it was considered important that research should be widely accessible and benefit a broad spectrum of individuals.

Research Letter – Research Priorities in the Management of Hidradenitis Suppurativa.

The priority offered to laser treatment (Options C, D, F and M), in parallel with a desire for wide-reaching research, might suggest a comparison of laser plus medical treatment versus medical alone or laser alone. A multi-arm study that allows for different medical treatments for people at different stages/severity of disease could build the evidence base for laser treatment in an inclusive fashion.

Geographic variation in treatment availability was recognised and improved accessibility was considered an important goal for any future HS research. The potential for HS flare-clinics was recognised in this – supporting quicker access to appropriate healthcare for those experiencing a flare.

Before concluding we should recognise some limitations in our method. Participants may not be fully representative – only one GP participated, many of those with lived experience had already experienced multiple treatments, and participants were drawn solely from the United Kingdom. Whilst the hybrid meeting supported participation it may be that those joining online were less able to contribute.

This workshop was intended as a springboard for future HS RCTs. It builds upon insight gained during the THESEUS study and benefits from the participation of the network of clinicians, researchers, and members of the public involved in the delivery of THESEUS. With a network of potential recruiting centres already in place the THESEUS team are now well placed to develop the prioritised trials. We would encourage other researchers to consider the trial comparisons prioritised in our meeting as ways in which the treatment of HS might be advanced and improved.

Research Letter – Research Priorities in the Management of Hidradenitis Suppurativa.

Figure 1: from original list to prioritised trials.



Research Letter – Research Priorities in the Management of Hidradenitis Suppurativa.

Refs:

1. Naik HB, Lowes MA; A Call to Accelerate Hidradenitis Suppurativa Research and Improve Care-Moving Beyond Burden. *JAMA Dermatol* 2019;**155**(9):1005-1006. doi: 10.1001/jamadermatol.2019.1105.
2. Ingram JR, Woo PN, Chua SL, et al.; Interventions for hidradenitis suppurativa: a Cochrane systematic review incorporating GRADE assessment of evidence quality. *Br J Dermatol* 2016;**174**(5):970-8. doi: 10.1111/bjd.14418.
3. Bates J, Stanton H, Cannings-John R, et al.; Treatment of Hidradenitis Suppurativa Evaluation Study (THESEUS): protocol for a prospective cohort study. *BMJ Open* 2022;**12**(4):e060815. doi: 10.1136/bmjopen-2022-060815.
4. Thorlacius L, Ingram JR, Villumsen B, et al.; A core domain set for hidradenitis suppurativa trial outcomes: an international Delphi process. *Br J Dermatol* 2018;**179**(3):642-650. doi: 10.1111/bjd.16672.
5. Murphy MK, Black NA, Lamping DL, et al.; Consensus development methods, and their use in clinical guideline development. *HTA* 1998;**2**(3).