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An observational study of medical and surgical treatments for hidradenitis suppurativa

Submission date
01/08/2019

Recruitment status
No longer recruiting

Registration date
09/08/2019

Overall study status
Completed

Last Edited
01/03/2024

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hidradenitis suppurativa (HS) is a long term, painful skin condition. It involves boils in areas such as the armpit and groin. It affects young adults of working age. HS has a big effect on quality of life due to pain, scarring and release of pus. It also affects sex and relationships. This study will provide vital information to answer questions that were identified as priority areas for research by patients with HS and the doctors and nurses who treat them. The aim is to inform the design of future HS trials and to understand how HS treatments are currently used. This involves five steps:
1. Describe the treatments used around the country (particularly the type of operation, which can vary from centre to centre)
2. See whether patients might consider joining a research study in the future and which treatment(s) they would prefer
3. Define how patients with HS are currently seen within the health service. Learn what influences patients' and clinicians' treatment choices
4. Select the best ways of measuring response to treatment (outcome measures)
5. Ask patients and doctors to agree the best design for future HS studies

Who can participate?
Patients aged 18 years and over with active HS of any severity that is not adequately controlled by current treatment

What does the study involve?
Patients with HS are invited to join the study as volunteers. By inviting people who are treated by skin doctors and those treated by surgeons, the researchers should receive information about a range of treatments. The volunteers pick from the range of treatments available locally and, for the year after, the researchers record what happens to them. They measure how well the treatment has worked using recommended questionnaires and help to interpret the questionnaire results by checking what changes in score matter to patients and whether the questionnaires are suitable for normal clinical practice. During the study the surgical and laser operations are video recorded to make a training video for future studies.

What are the possible benefits and risks of participating?
Deroofing and laser hair removal, when offered by a recruiting centre, are not usually available for HS in the UK (they are available in several other countries). Participants will also be contributing to standardising outcome measures for future HS trials. Techniques used for surgical procedures are part of standard surgical skills, but all participating surgeons will complete a specialised training package before performing deroofing. Participation in the study will require completion of some additional questionnaires not currently used in routine HS care that will take up additional time during clinic appointments.

Where is the study run from?
1. University Hospital of Wales
2. Hull York Medical School
3. Royal Free Hospital
4. Newcastle Upon Tyne Hospital
5. Broomfield Hospital
6. Guy's & St Thomas Hospitals
7. Barnsley Hospital
8. Stirling Community Hospital
9. Salisbury Hospital
10. Nuffield Orthopaedic Centre

When is the study starting and how long is it expected to run for?
April 2019 to March 2022

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
1. Janine Bates
batesmj@cardiff.ac.uk
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
266172

Protocol serial number
HTA 17/98/01, SPON 1734-19

Study information

Scientific Title
Treatment of hidradenitis suppurativa evaluation study (THESEUS)

Acronym
THESEUS

Study objectives
To inform the design of future HS RCTs and to understand how HS treatments are currently used.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/09/2019, Wales Research Ethics Committee 4 Wrexham (Health and Care Research Wales Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0) 7976 982591; Wales.REC4@wales.nhs.uk), REC ref: 19/WA/0263

Primary study design
Observational

Study design

Prospective cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hidradenitis suppurativa

Interventions
1. Oral doxycycline 200 mg OD for 6 months initially
2. Oral clindamycin and rifampicin both 300 mg BD as a combined course for 10 weeks
3. Laser treatment
4. Deroofing of sinus tracts
5. Conventional surgery (narrow or wide excision, with a range of closure methods)

Participants choose their preferred treatment intervention and have follow ups every three months up to 12 months. They can swap treatment intervention during this time, should they wish to do so.

Intervention Type
Mixed

Primary outcome(s)
Proportion of participants who are eligible, and hypothetically willing, to use the different treatment options, measured using screening log at baseline

Key secondary outcome(s)
1. Proportion of participants choosing each of the study interventions, with reasons for their choices, measured using descriptive statistics of each group membership for each intervention at baseline/month 0
2. Proportion of participants who switch treatments during the study follow-up period, with reasons for switch, measured using questionnaires during the study follow-up period
3. Treatment fidelity measured using questionnaire at 3, 6, 9 and 12 months
4. Loss to follow-up rates measured using percentage of consented participants failing to attend appointments over 12 months
5. Efficacy outcome estimates after 6 months' of follow up to inform outcome measure instruments' responsiveness (minimum important difference, MID):
5.1. Pain measured using a numeric rating scale at the baseline appointment and then on a daily basis for the first 12 weeks following treatment commencement via mobile telephone text message
5.2. HS-specific quality of life measured using HiSQOL
5.3. Global assessment (average change over time estimation)
5.4. Progression of course (flare frequency) (average change over time estimation)
5.5. Physical signs (average change over time estimation)
5.6. Symptoms (drainage resulting in need for dressings and fatigue) (average change over time estimation)
5.7. Generic quality of life measured using EQ-5D
The researchers will report completeness of each outcome at each timepoint (0, 3, 6, 9 and 12 months)

Completion date

31/03/2022

Eligibility

Key inclusion criteria
1. Adults at least 18 years old with active HS of any severity
2. Diagnosis confirmed by recruiting clinician with experience of HS care
3. HS not adequately controlled by current treatment
4. At least one of the five study interventions is appropriate for participant's care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
151

Key exclusion criteria
1. Unable or unwilling to give informed consent
2. Pregnancy or breastfeeding

Date of first enrolment
18/02/2020

Date of final enrolment
28/07/2021

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
University Hospital of Wales
Heath Park Way
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Newcastle Upon Tyne Hospital
Clayton Road
Newcastle Upon Tyne
United Kingdom
NE2 1JP

Study participating centre
Broomfield Hospital
Court Road
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Guys & St Thomas Hospitals
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Barnsley Hospital
Gawber Road
Barnsley
United Kingdom
S75 2EP

Study participating centre
Stirling Community Hospital
Livilands Gate
Stirling
United Kingdom
FK8 2AU

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford
United Kingdom
OX3 7HE

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Oxford
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OX3 7HE

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/10/2023	16/10/2023	Yes	No
Results article		01/12/2023	28/12/2023	Yes	No
Protocol article		21/04/2022	25/04/2022	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version V1.0	25/07/2019	09/08/2019	No	No