

An observational study of medical and surgical treatments for hidradenitis suppurativa

Submission date 01/08/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/03/2024	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> 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
2. Dr John Ingram
ingramjr@cardiff.ac.uk

Contact information

Type(s)

Public

Contact name

Ms Janine Bates

Contact details

Centre for Trials Research
College of Biomedical and Life Sciences
Cardiff University
7th Floor, Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom

CF14 4YS
+44 (0)29 20687616
batesmj@cardiff.ac.uk

Type(s)
Scientific

Contact name
Dr John Ingram

Contact details
Division of Infection & Immunity
Cardiff University
Cardiff
United Kingdom
CF10 4AT
+44 (0)29 2074 2190
ingramjr@cardiff.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
266172

ClinicalTrials.gov number

Secondary identifying numbers
HTA 17/98/01, SPON 1734-19, IRAS 266172

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

Study design

Prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/04/2019

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

150 participants

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

England

Scotland

United Kingdom

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
United Kingdom
OX3 7HE

Sponsor information

Organisation

Cardiff University

Sponsor details

Research Governance Team
Research and Innovation Services
McKenzie House, 7th floor
30-36 Newport Road
Cardiff

Wales
United Kingdom
CF24 ODE
+44 (0)29 2087 9277
resgov@Cardiff.ac.uk

Sponsor type

University/education

ROR

<https://ror.org/03kk7td41>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The researchers will present the findings from the study at international meetings of doctors and researchers. They will publish them openly in journals, where anybody can see them. The HS Trust patient support group will host links to these publications on its website, including a plain language summary and podcasts.

Results from all studies (cohort, mixed methods and outcome validation studies) will be presented and discussed during the final consensus workshop. This information will be used to inform discussions over preferred study design and priority research questions.

Results from the study will be distilled into a plain language summary that will be written in collaboration with the patient partners. It will be hosted on the HS Trust website and disseminated further via links in social media posts, such as the HS Trust, relevant research networks and journal Twitter feeds.

The researchers will set up a THESEUS study website that will provide information about the study, both during the project and hosting the plain language summary and other outputs afterwards. The website will be designed so that the information is accessible to all stakeholders.

Patient and public involvement

The President of the HS Trust has been a member of the bid team from the beginning and will be part of the group that manages the study. She led the patient survey, using the HS Trust website and social media. The survey, completed by 358 people, helped to shape the study plan. Throughout the THESEUS study, the researchers will interview participants about their study experiences. They will ask about reasons why they might or might not, take part in future studies. A group of people with HS and doctors/nurses/researchers involved in the study will meet in a workshop at the end of the study. This will be used to agree the best designs for future HS research.

Intention to publish date

20/12/2023

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?
Protocol file	version V1.0	25/07/2019	09/08/2019	No	No
Protocol article		21/04/2022	25/04/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		12/10/2023	16/10/2023	Yes	No
Results article		01/12/2023	28/12/2023	Yes	No