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Developing a checklist to allow accurate diagnosis of vulval lichen sclerosus

Submission date
25/04/2024

Recruitment status
Recruiting

Registration date
17/06/2024

Overall study status
Ongoing

Last Edited
26/06/2025

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Vulval lichen sclerosus (LS) is an inflammatory vulval skin condition that typically presents as skin itching, thinning, splitting and whitening. If left untreated, this can progress to irreversible sticking together (scarring) of the skin. Discomfort caused by LS can therefore impact daily living, making activities such as sitting, walking, going to the toilet and sexual intercourse difficult. There is currently no specific checklist that can guide the diagnosis of vulval lichen sclerosus, and as such, the condition is often misdiagnosed, or that diagnosis is delayed. This study aims to improve the diagnosis of LS through testing an internationally expert-agreed 'checklist' (diagnostic criteria) in a clinical setting to help non-experts and patients identify LS more easily.

Who can participate?
Women (over 18 years of age) who have been referred to a skin specialist with a vulval skin complaint by their GP

What does the study involve?
Participants will attend a single research appointment where both the patient’s managing clinician and a second health professional who is blinded to the clinician's diagnosis will conduct separate vulval examinations, in addition to taking optional clinical photographs of the patient's LS condition. This will enable the assessment of how well the checklist can identify LS compared to other vulval complaints.

What are the possible benefits and risks of participating?
The research team cannot promise that the study will help participants, but the information gained from this study may help better diagnose other people with a vulval complaint. If the checklist can be successfully introduced into primary care, it could be used as a tool to pick up cases earlier, enabling quicker access to treatment. It is not anticipated that there will be any risks associated with participating in this study.

Where is the study run from?
University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
April 2023 to February 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Rosalind Simpson, Rosalind.simpson@nottingham.ac.uk

Study website
https://www.nottingham.ac.uk/go/shells

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332947

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 59725, NIHR301434, IRAS 332947

Study information

Scientific Title
Establishing effective diagnostic criteria for vulval lichen sclerosus: a diagnostic test accuracy study

Acronym
SHELLS

Study objectives
A validated checklist of signs and symptoms (diagnostic criteria) will help to improve the accurate diagnosis of vulval lichen sclerosus in primary care and the community.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/05/2024, London - Camberwell St Giles Research Ethics Committee (Georgian House, 64-68 Camberwell Church St, London, SE5 8JB, United Kingdom; +44 (0)2071048222; camberwellstgiles.rec@hra.nhs.uk), ref: 24/LO/0290

Study design
Observational cross-sectional

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Diagnostic

Participant information sheet

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

Health condition(s) or problem(s) studied
Vulval lichen sclerosus

Interventions
407 consecutive women (≥18 years of age) who have been referred to a skin specialist by their GP with a vulval skin complaint will be identified by the usual care team from clinic lists. Patients will then be sent the patient information sheet and expression of interest form ahead of their appointment at the specialist clinic. Patients will have the opportunity to discuss all aspects of the study and provide consent either at the appointment or in advance. Once the participant has consented, the research team will ask some demographic and clinical questions, and then both the patient's managing clinician and a second health professional who is blinded to the clinician's diagnosis will conduct separate vulval examinations. At one site (Nottingham), participants may be examined by a third blinded health professional. Optional clinical photographs will also be taken of the patient's LS condition. This will all occur in a single study visit that will last approximately 30 minutes. This information will be uploaded by the research site to the online database (REDCap) and the results will be analysed to assess the diagnostic accuracy of the criteria (from a previous electronic-Delphi consensus study registered at: https://www.nottingham.ac.uk/research/groups/cebd/documents/ls-protocol.pdf).

The 17 expert-agreed diagnostic criteria are:
• Changes in the anatomy of the genital area
• Response to topical corticosteroids
• Whiteness
• Itch
• Burying of the clitoral area
• Absence of vaginal involvement
• Fissuring
• Crinkly skin
• Bruising/bleeding under the skin
• Fissuring at the back entrance to the vagina
• Pain/soreness unrelated to sexual activity
• Pain/soreness related to sexual activity
• Skin thickening
• Loss of skin stretchiness
• Erosions
• Irritation
• Perianal fissure

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To test a list of 17 expert-agreed diagnostic criteria measured using vulval clinical examination at one timepoint during a clinical consultation, to establish the best predictors for vulval lichen sclerosus and subsequently develop a diagnostic tool

Secondary outcome measures
Development of training resources/manual using qualitative methods, including input from patients and health professionals, to support the use of a future diagnostic tool at the end of the data collection

Overall study start date
14/04/2023

Completion date
01/02/2027

Eligibility

Key inclusion criteria
1. Female
2. >=18 years of age
3. New presentation to a specialist clinic (secondary care or community hub) with a vulval skin complaint

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 407; UK Sample Size: 407

Key exclusion criteria
1. Inability to provide informed consent
2. Patients with surgical alteration of vulval skin as part of gender reaffirming surgery, or patients not born with a vulva
3. More than 2 weeks since initial consultation from managing clinician

Date of first enrolment
27/09/2024

Date of final enrolment
01/08/2026

Locations

Countries of recruitment

England

Scotland

United Kingdom

Wales

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre

James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Torbay and South Devon NHS Foundation Trust
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Southampton University Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter

United Kingdom
EX2 5DW

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Study participating centre
Princess of Wales Hospital
Coity Road
Bridgend
United Kingdom
CF31 1RQ

Study participating centre
Pinderfields and Pontefract Hospitals NHS Trust
Rowan House
Pinderfields General Hospital
Aberford Road
Wakefield
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WF1 4EE

Study participating centre
Bedfordshire Hospitals NHS Foundation Trust
Lewsey Road
Luton
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LU4 0DZ

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
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Sponsor type
University/education

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ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journals of relevant medical specialities (e.g. in dermatology, gynaecology and general medicine)

Intention to publish date
01/12/2027

Individual participant data (IPD) sharing plan
The datasets analysed during the current study will be available upon request from the University of Nottingham (SHELLS@nottingham.ac.uk), a minimum of 6 months after publication

of the main results paper. Access to the data will be subject to review of a data sharing and use request by a committee including the CI and sponsor and will only be granted upon receipt of a data sharing and use agreement. Any data shared will be anonymised which may impact on the reproducibility of published analyses. Participants will provide consent for information obtained from their participation in the study to be anonymously shared.

IPD sharing plan summary

Available on request