Developing a checklist to allow accurate diagnosis of vulval lichen sclerosus

Submission date	Recruitment status	[X] Prospectively registered
25/04/2024	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
17/06/2024	Ongoing	Results
Last Edited	Condition category	Individual participant data
22/10/2025	Skin and Connective Tissue Diseases	[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

Contact information

Type(s)

Scientific

Contact name

Dr Rosalind Simpson

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Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

332947

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

United Kingdom

England

Scotland

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 United Kingdom WF1 4EE

Study participating centre Bedfordshire Hospitals NHS Foundation Trust

Lewsey Road Luton United Kingdom LU4 0DZ

Study participating centre Royal Victoria Infirmary

Queen Victoria Road Newcastle upon Tyne United Kingdom NE1 4LP

Study participating centre Royal Victoria Infirmary

Queen Victoria Road Newcastle upon Tyne United Kingdom NE1 4LP

Study participating centre North Devon District Hospital

Raleigh Park Barnstaple United Kingdom EX31 4JB Study participating centre **University Hospital of Wales** Heath Park Cardiff United Kingdom **CF14 4XW**

Sponsor information

Organisation

University of Nottingham

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

Government

Funder Name

NIHR Academy

Results and Publications

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

Study outputs

Output type **Details** Date created Date added Peer reviewed? Patient-facing? Participant information sheet 11/11/2025 11/11/2025 No