

Developing a checklist to allow accurate diagnosis of vulval lichen sclerosis

Submission date 25/04/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/06/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/03/2026	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Vulval lichen sclerosis (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 sclerosis, 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

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
332947

Central Portfolio Management System (CPMS)

59725

National Institute for Health and Care Research (NIHR)

301434

Study information

Scientific Title

Establishing effective diagnostic criteria for vulval lichen sclerosis: 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 sclerosis 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 sclerosis

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/lis-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

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 sclerosis 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

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

Female

Total final enrolment

0

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

England

M13 9WL

Study participating centre

Salford Royal

Stott Lane
Salford
England
M6 8HD

Study participating centre

Grampian

Summerfield House
2 Eday Road
Aberdeen
Scotland
AB15 6RE

Study participating centre

Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus

Nottingham University Hospital
Derby Road
Nottingham
England
NG7 2UH

Study participating centre

James Cook University Hospital

Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre

Torbay and South Devon NHS Foundation Trust

Torbay Hospital
Newton Road
Torquay
England
TQ2 7AA

Study participating centre

Sunderland Royal Hospital

Kayll Road
Sunderland
England
SR4 7TP

Study participating centre

Southampton University Hospital

Tremona Road
Southampton
England
SO16 6YD

Study participating centre

County Durham and Darlington NHS Foundation Trust

Darlington Memorial Hospital
Hollyhurst Road
Darlington
England
DL3 6HX

Study participating centre

Royal Devon University Healthcare NHS Foundation Trust

Royal Devon University NHS Ft
Barrack Road
Exeter
England
EX2 5DW

Study participating centre

Ninewells Hospital

Ninewells Avenue
Dundee
Scotland
DD1 9SY

Study participating centre

Princess of Wales Hospital

Coity Road

Bridgend
Wales
CF31 1RQ

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

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

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
NE1 4LP

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Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
NE1 4LP

Study participating centre
North Devon District Hospital
Raleigh Park
Barnstaple
England
EX31 4JB

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

Study participating centre
Oxleas NHS Foundation Trust
Pinewood House
Pinewood PLACE
Dartford
England
DA2 7WG

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes