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A feasibility study to evaluate platelet-rich plasma and autologous lipotransfer to treat vulval fibrosis in lichen sclerosus

Submission date
07/01/2025

Recruitment status
Recruiting

Registration date
09/10/2025

Overall study status
Ongoing

Last Edited
09/10/2025

Condition category
Urological and Genital Diseases

[_] 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 (VLS) is an itchy condition affecting the skin around the entrance to the vagina (vulva). In severe cases, it causes scarring and fusion of parts of the vulva, leading to painful skin tears, and difficulty in having sex and going to the toilet. VLS affects women of any age but is most diagnosed before puberty and after menopause. Treatment includes lifelong use of creams that reduce inflammation (angriness) and irritation of the skin called steroids. For most patients, the condition is controlled by this treatment but some experience ongoing symptoms, scarring and skin thickening. Recent studies have introduced two potential surgical treatments: autologous fat grafting (AFG) and platelet-rich plasma (PRP) which may improve VLS symptoms and reduce scarring. Fat grafting involves collecting fat from the patient's own body (autologous) and injecting it into the vulva. PRP is obtained from the patient's blood, prepared specially, and then injected into the vulva. This is a feasibility (pilot) study in which patients will either undergo one of these new treatments or use steroid cream only to check if these treatments are acceptable and how to best measure their effectiveness. The study will investigate if it is possible to perform a larger trial in multiple hospitals in the future to find out if these treatments work.

Who can participate?
Adult females (aged 18 years or older) with expert-diagnosed vulval lichen sclerosus and vulval fibrosis caused by the disease.

What does the study involve?
This study will involve up to 75 women with VLS. They will be allocated randomly and equally into three groups: fat grafting, platelet-rich plasma and steroid cream only. Patients in the surgical groups will undergo one surgery and will continue using the steroid cream. Participants will complete questionnaires about their symptoms, quality of life and sexual function. Any improvements will be assessed by analysing photographs of the vulva and measuring the thickness of the vulval skin using specialised equipment. Patients will be followed up for six months.

What are the possible benefits and risks of participating?
Benefits:
If allocated to one of the surgical arms (PRP or AFG) patients will be offered one surgical procedure which, based on current evidence, may improve signs and symptoms of VLS. Patients in the standard-of-care group will be offered one of the surgical treatments at the end of the study. This study will allow us to assess whether performing a larger trial would be possible. This is the first step in assessing the effectiveness of the proposed treatments which if found to be effective, may become another treatment option for VLS.

Risks
All surgical procedures will be carried out under general anaesthesia. Patients' suitability and anaesthetic risk will be assessed by a consultant anaesthetist. Both surgical procedures have minor side effects which are not serious and include bruising, tenderness and swelling.

Where is the study run from?
1. Royal Free Hospital is the primary study recruitment and treatment centre. All patients will be followed up there.
2. Nottingham University Hospital is the second patient identification centre.
3. Surgical procedures will take place either at Royal Free Hospital or Hadley Wood (a private facility, as a part of the waiting list initiative).

When is the study starting and how long is it expected to run for?
January 2025 to November 2027

Who is funding this study?
The National Institute for Health and Care Research Research (NIHR) Research for Patient Benefit (RfPB) Programme grant

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333113

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR206718, CPMS 59835

Study information

Scientific Title
A feasibility randomised controlled trial evaluating PlatElet-rich plasma and Autologous lipotransfer in addition to topical corticosteroids to treat vulval fibrosis in Lichen Sclerosus (PETALS)

Acronym
PETALS

Study objectives
This study aims to assess the feasibility of conducting a large randomised controlled study which would evaluate the effectiveness of platelet-rich plasma and autologous lipotransfer procedures in addition to topical corticosteroids (standard of care) and compared to the standard of care alone to treat vulval fibrosis in lichen sclerosus

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/03/2025, London Camden and King's Cross Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048086; camdenandkingscross.rec@hra.nhs.uk), ref: 25/LO/0107

Study design
Single centre interventional randomized feasibility controlled trial with a second patient identification centre

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of vulval fibrosis in vulval lichen sclerosus

Interventions
This is a single-blind (blinded assessors) randomised controlled feasibility trial.

Trained members of the research team and clinical collaborators on the Delegation of responsibility log at Royal Free Hospital, Nottingham University Hospital will identify eligible participants attending Dermatology and Vulval clinics and inform them about the trial. Participants will also be recruited through posters, leaflets, scientific societies and patient forums.

All potentially eligible patients who express initial interest in taking part will be given Patient Information Sheets and Consent Forms. This will be followed by a phone call from a member of the research team to discuss the study details and confirm their interest and eligibility.

If eligible and willing to take part, potential participants will be invited to attend a clinic appointment at Royal Free Hospital. All patients will be given time to ask questions before they provide written informed consent witnessed by a member of the study team. A copy of the signed consent form will be given to the patient, another placed in the patient’s notes, and the researchers will retain a further copy.

If patients do not consent to take part in the study, they will be asked to complete a feedback form to help us understand barriers to recruitment.

They will then be randomised into one of the trial arms and undergo the baseline assessments. Following confirmation of eligibility and written informed consent, participants will be randomised using a centralised online randomisation system (https://sealedenvelope.com/) to ensure randomisation concealment and minimise bias.

Randomisation and allocation will be overseen by the trial coordinator who will not be involved in the recruitment, treatment or assessment. All patients will be started on a standardised TCS (Standard of care - 'SoC') and vulval care regimen at the baseline visit after randomisation.

Randomisation will be 1:1:1 to three treatment arms:
1. SoC alone
2. Autologous fat graft (AFG) + SoC
3. Platelet-rich plasma (PRP) + SoC

Patients in two surgical arms will undergo a procedure under general anaesthesia where AFG and PRP are collected and either AFG or PRP is injected into the vulval area. Patients will be blinded to the injection they receive. To reduce the risk of slow study progression due to NHS waiting times, patients will be operated through a waiting list initiative which will be factored in the excess treatment costs.

A pragmatic approach of allowing patients to continue a potent TCS which they are known to tolerate will be used, as agreed with dermatology. A maintenance regimen of twice weekly (non-consecutive days) will occur. If patients experience a flare-up of VLS signs and symptoms an increase will be advised (TCS daily for seven days) as standard practice.

The study will involve a Consultant Dermatologist review as adjuvant management if clinically indicated by the research team to manage patients whose disease is poorly controlled.

All patients will be followed up for 6 months.

All patients will be on topical corticosteroids and the frequency of use will be monitored through patient diaries and assessed during the follow-up. The study will explore the use of electronic reminders and patient diaries to assess which format works best for patients and maximises data completeness.

Patients randomised to the surgical arms (PRP or AFG) will undergo additional baseline assessments on the day of surgery. They will be able to discuss any urgent queries with a trained clinical research team member via the PETALS trial helpline. A member of staff will be allocated to reply to patients' queries. This service will be available from Monday to Friday and will help us to work closely with our patients.

Participants in the AFG and PRP arms will be contacted by a research team member via telephone 7 and 14 days postoperatively to monitor for any complications and offer advice if necessary. All patients will attend follow-up visits at 3 months and 6 months. Patients will be reimbursed for travel. Each follow-up visit will last approximately one hour.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Recruitment rate recorded as the proportion of eligible patients willing to be randomised measured using study records at one time point

Key secondary outcome(s))

1. The average number of patients recruited per month and the total number of recruited patients at the end of the study measured using study records at one time point
2. The rate of withdrawal from the study, data collection completeness, and the impact of the distance travelled to the treatment centre on the patient retention rate are measured using study records at one time point
3. The acceptability of the proposed treatments to patients and clinicians is assessed throughout the study through qualitative interviews
4. Adherence to the trial protocol measured using patients' steroid cream diaries and follow-up visit attendance and adequate timing of outcome assessments evaluated at the end of the study via qualitative questionnaires completed by clinicians and patients.
5. The feasibility of setting up a second treatment centre in Nottingham evaluated via qualitative questionnaires on cost, available expertise and facilities, and training needs and the evaluation of the number of centres required nationally to run a multicentre trial measured at the end of the study measured using the number of patients required to run an adequately powered randomised controlled trial, recruitment rate and proportion of patients willing to be randomised in this feasibility trial, expertise available nationally and patient availability (qualitative questionnaires disseminated in collaboration with national vulval lichen sclerosus organisations, dermatology and gynaecology associations).
6. The appropriate outcome assessments and their timing. Investigated measures will be assessed at baseline, 3 and 6 months and will include:
6.1. Patient-reported signs and symptoms – Vulvovaginal Symptom Questionnaire (VSQ), Visual assessment score (VAS) for soreness, itching, burning, dyspareunia, The Female Genital Self-Image Scale (FGSIS), Clinical Lichen Sclerosus Score (CLISSCO) subjective part, The Vulvar Pain Assessment Questionnaire (VPAQ), Pain Anxiety Symptom Scale Short Form 20 (PASS-20), Genital Appearance Assessment Scale (GAAS)
6.2. Patient-reported sexual function - Female sexual function index (FSFI), Female Sexual Distress Scale (FSDS)
6.3. Patient-reported psychological status and QoL questionnaires - Vulvar quality of life index (VQLI), Dermatology Life Quality Index (DLQI), Skindex-16, Short Form Survey 12 (SF-12), Hospital Anxiety and Depression Scale (HADS), Relationship Assessment Scale (RAS)
6.4. Clinician-reported outcomes – Vulvar Architecture Severity Scale (VASS), CLISSCO objective part, Clitoral phimosis, Interlabial sulci involvement, Vulvar introitus narrowing (CIV) score
6.5. Imaging - 3D Vectra h1 & 2D photography, measurement of microcirculation by laser speckle contrast imaging and visual capillary microscope (HVC)
6.6. Skin fibrosis - FibroMeter, cutometer, durometer, high-frequency ultrasound
7. Rate of adverse events assessed throughout the study.
8. Acceptability to include a sham intervention to patients and clinicians in a future randomised prospective trial assessed through qualitative interviews at 3 and 6 months.
9. Feasibility of collecting health economics data and preliminary estimates of cost-effectiveness at baseline, 3 and 6 months using:
9.1. Healthcare resource utilisation – Client Service Receipt Inventory (CSRI)
9.2. Health-related QoL – EQ-5D-5L
9.3. Impairments in work and activities - Work Productivity and Activity Impairment (WPAI)
10. The most appropriate way to communicate with patients to disseminate the results of the study and increase awareness of the proposed treatments and the definitive trial assessed through qualitative interviews at 6 months follow-up.
11. The most appropriate way to communicate with clinicians to disseminate the results of the study and increase awareness of the proposed treatments and the definitive trial assessed through qualitative interviews throughout the study.

Completion date
01/11/2027

Eligibility

Key inclusion criteria
1. Adults (>18 years)
2. Female sex
3. Patients who live in the UK
4. Patients with expert-diagnosed clinical and/or histological diagnosis of VLS
5. Able to give informed consent
6. Able to communicate in English
7. Structural changes secondary to VLS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Active malignancy or previous diagnosis of intraepithelial neoplasia/carcinoma of the vulva
2. Previous vulval AFG or PRP
3. Body mass index <18.5 or >35.0
4. Contraindications to general anaesthetic
5. Active infection that precludes fat harvest, AFG or PRP injection
6. Pregnancy, breastfeeding or planning for pregnancy during the study period
7. Connective tissue and autoimmune diseases and diseases which affect the vulva

Date of first enrolment
01/07/2025

Date of final enrolment
01/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Free London NHS Foundation Trust
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Study participating centre
Nottingham University Hospitals NHS Trust - City Campus
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Sponsor information

Organisation
Royal Free London NHS Foundation Trust

ROR
https://ror.org/04rtdp853

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date