

**Patient Consent – Leg Ulcer Pathway Acceleration**



**Informed Consent form for patients participating in the Venous Leg Ulcer Pathway Acceleration**

**This Informed Consent Form has two parts:**

* **Information Sheet (to share information about the research with you)**
* **Certificate of Consent (for signatures if you agree to take part)**

**You will be given a copy of the full Informed Consent Form**

**PART I: Information Sheet**

**Introduction**

We have worked to implement a more effective management protocol to identify, diagnose, and treat patients with venous leg ulcers (VLU). Our goal is to ensure that more patients with VLU are healed in a timely fashion and to decrease the recurrence rates of these wounds.

The improved management protocol ensures that patients are sent to the right practitioners to better assess their condition and assign them to the appropriate approved clinical treatments. This study does not involve testing new treatments and only seeks to provide more consistent guideline-backed care to all patients with VLU.

If you have any questions, please feel free to ask any practitioner involved with the protocol for clarification.

**Purpose**

Venous leg ulcers (VLU) represent a highly burdensome disease that, in the United Kingdom alone, affects over 250,000 patients and costs roughly £1 billion annually to manage, with some estimates as high as £1.3 billion. The experience for patients living with venous leg ulcers is often painful and distressing. Normal independent life can be significantly inhibited, resulting in more frequent social isolation; VLUs are a major cause of morbidity and significantly decrease health-related quality of life in the people that it affects.

Current standard of care for venous leg ulcers is disorganized and primarily relies on implementation of superficial treatments, such as topical ointments and compressive bandaging. While an important part of patient management, these superficial treatments do not often address the underlying causal factors of disease and, as a result, patient’s wounds don’t heal quickly and don’t stay healed once they have. A protocol to standardize improved management of this disease state across the UK has the potential result in significantly improved quality of life outcomes for hundreds of thousands of patients and hundreds of millions of pounds in cost savings to the NHS system.

**Protocol Hypothesis**

We hypothesize that identification and treatment of the underlying causal mechanisms via standardized diagnostics and interventional surgical procedures will improve patient clinical outcomes such as wound time to healing, heal rate, and recurrence rate.

This protocol does not involve testing any new treatments, and only seeks to provide care in accordance with NICE guidance.

**Participant selection**

All patients with venous leg ulceration at the participating clinics have been identified and will be asked to participate in this improved management protocol.

**Voluntary Participation**

Your participation in this protocol is voluntary. If you choose not to participate in this improved management protocol, you will be offered the treatment that is routinely offered in this clinic/hospital for venous leg ulceration. You may change your mind later and stop participating even if you agreed earlier.

**Procedures and Protocol**

1. **Initial Assessment**
   1. You and your care team will assess your past medical history, the status of your wound, and will conduct baseline questionnaires and tests to assess your current medical status.
2. **Clear Diagnosis**
   1. You will be referred to one or more diagnostic appointments where they will look at the veins in your leg to determine potential root causes of your wound.
   2. They will conduct an ultrasound scan and may also use additional scans, like an MRI or CT, to assess vein health along your entire lower body.
   3. Depending on what these tests show, your team may recommend specific treatments to address the underlying causes of your ulcer.
      1. One common underlying cause is damaged valves and backwards flowing blood (reflux) in your veins.
      2. Another common cause is an upstream blockage in your vein that needs to be opened to restore healthy flow of blood out of your leg.
3. **Root Cause Treatment**
   1. Depending on your diagnostic results, you will be offered minimally invasive surgical options to help you heal your ulcer and to stay healed. Our goal is not only to heal your ulcer but to also prevent you from developing more ulcers in the future (recurrence).
   2. If the physicians identify superficial vein reflux, you may be referred to a procedure where they are able to close down the damaged veins. This is called a superficial vein ablation procedure.
   3. If the physicians identify an upstream blockage or obstruction, you may be referred to a procedure where they will open up this blockage. This procedure involves placing a stent inside your vein to help restore healthy blood flow out of your leg.
4. **Follow-Up**
   1. After your procedure, you will attend follow-up appointments in the clinic to see how your leg ulcer is healing and to ensure that you have the additional care that you need.



**Confidentiality**

Your health data will be stored in a secure database consistent with national health facility standards.

**Sharing the Results**

Final results of the optimized patient care pathway will be distributed in the form of podium presentations and academic journal publications to demonstrate the clinical and economic impact of the study. Your de-identified health data may be used by an external clinical research organization to quantify the value that this improved pathway brings to VLU patients and the hospital system.

**PART II: Certificate of Consent**

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this protocol.**

**Print Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**