The DAVE study team are looking for Participating Organisations/Principal Investigators to recruit to the study. Contact Francine Heatley (f.heatley@imperial.ac.uk; Trial Manager) for more information about how you can take part.

Title: Decellularised Dermis Allograft for the Treatment of Chronic Venous Leg Ulceration (DAVE)

Purpose of this Study: To determine whether the use of a decellularised dermis (DCD) allograft in addition to compression therapy, promotes healing in chronic venous leg ulceration compared to compression therapy alone.

Funder: JP Moulton Charitable Trust (NIHR portfolio adopted)

Design: Multi-centre, prospective, pragmatic, blinded outcome assessment, randomised controlled trial. The trial will follow patients up for 12 months and will be conducted in approximately 20 secondary care Trusts in the United Kingdom.

Sample Size: A total of 196 patients will be recruited: approximately 98 to each trial arm.

Eligibility criteria:

Inclusion criteria

- ≥18 years or older (no upper age limit)
- The ability to consent to participation
- A diagnosis of venous leg ulceration
- Documented venous incompetence on duplex ultrasound or handheld continuous wave Doppler
- Index ulcer wound that has been present for at least 6 months
- Index ulcer wound size ≥ 2 cm2.
- ABPI ≥ 0.8

Exclusion criteria

- A diagnosis of sickle cell
- Unable to receive one or more of the randomised treatment strategies for any reason at the discretion of the attending clinical team (e.g. known allergies to dCELL dermis preparation components)
- A clinically infected ulcer defined as evidence of erythema, cellulitis or systemically unwell
- Treatment with biomedical/topical growth factors within previous 30 days
- Previous history of an inability to tolerate compression therapy
- Foot ulcer (i.e. below the ankle)

Intervention: The DCD graft is made from human skin from deceased donors which has been processed to remove the human cells and leave a matrix behind. DCD contains no human cells, unlike other donated skin grafts, which means that it is unlikely to be rejected.

Endpoints:

Primary outcome
The proportion of participants with a healed index ulcer at 12 weeks after randomisation.

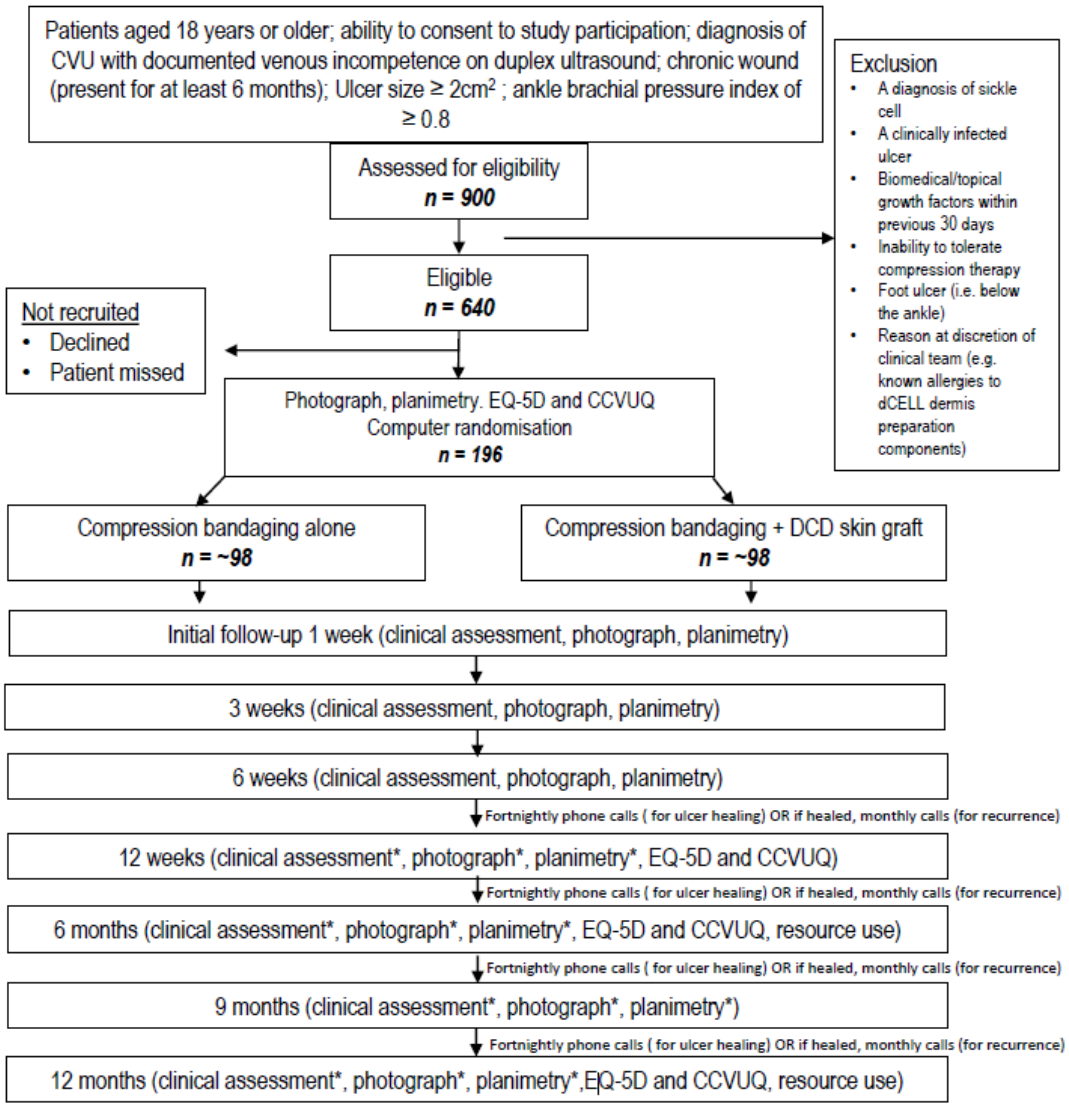
Secondary outcomes

- Time to index ulcer healing from randomisation
- The percentage change in index ulcer area at 12 weeks from randomisation
- The proportion of participants with a healed index ulcer at 12 months from randomisation
- The proportion of those whose index ulcer healed for whom an ulcer recurred at the index site within 12 months from randomisation
- EQ-5D questionnaire & CCVUQ at 12 weeks, 6 months and 12 months from randomisation
- Economic evaluation based on a modelling exercise and patient resource use
- Incremental cost-per-QALY (quality adjusted life year) ratio from the EQ-5D questionnaire, with appropriate sensitivity analysis

Follow-up: 1 week, 3 weeks, 6 weeks, 12 weeks, 6 months, 9 months, 12 months

Site reimbursement: £720 per participant randomised (£400 for randomisation, £320 for complete follow-up) plus £647 per site for monitoring and archiving. Camera and tracing grids provided.

Evaluation of decellularised dermis allograft for the treatment of chronic venous ulcers



Primary outcome
Proportion of healed ulcers at 12 weeks

*unless ulcer healed. Photo verification visits will be performed upon notification of ulcer healing if between clinic visits. Once the ulcer is confirmed as healed monthly telephone calls will be performed to check for recurrence

ALL participants will be followed up for 12 months

Secondary outcome measures

- Time to ulcer healing
- The % change in index ulcer area in cm2 at 12 weeks from randomisation
- The proportion with a healed index ulcer at 12 months from randomisation
- The proportion whose index ulcer healed for whom an ulcer recurred at the index site within 12 months from randomisation
- Quality of life – EQ-5D, Charing Cross venous ulcer questionnaire
- Cost-effectiveness