

MIDFUT study – centre requirements

- Provide a multidisciplinary diabetic foot ulcer service with input/access to podiatry, a diabetologist, vascular and orthotics.
- Provide delivery of study interventions as below;
Hydrosurgical debridement (VERSAJET)
 - If currently in use at the Trust can it be used for trial participants in the diabetic foot ulcer clinic?
 - If not currently in use a VERSAJET console will be provided. Consideration to the following;
 - A dedicated room for the console can be used
 - Infection control considerations 1 meter area around the bed/couch is required.
 - Storage of the console
 - Ordering process for disposables – need a supply to be available for day of randomisation

Decellularised dermal allograft (DCD)

- Secure storage & weekly temperature monitoring (temperature range 0-40 degrees): thermometer and temperature monitoring log will be provided.

Negative pressure wound therapy (NPWT)

- If currently in use are pumps available for trial participants?
- If no, or if not in use, Renasys Go pumps will be provided. Consideration to the following;
 - Secure storage of the consoles
 - Ordering process for disposables – need a supply available for day of randomisation

MIDFUT staff capacity/dedicated time requirements

- Screening: Will take place in the diabetic foot ulcer clinics – can the research staff access potential participants
- Randomisation/baseline visit: This may require up to 2 hours to confirm eligibility & apply treatment (NPWT participants are seen at week 1 and 2 for dressing change/NPWT removal).
Note: the randomised treatment strategy is applied **once only** at the randomisation/baseline visit and we are asking for 1-2 randomisations **per month**
- Follow up visits at week 2, 4, 12, 20 and 52: data collection, wound tracing and photography only.
- Blinded assessor required at week 4 and if the participant reports healing.

MIDFUT financial arrangements

- Where required a VERSAJET console and training will be provided at site free of charge
- Where required up to 3 Renasys Go negative pressure wound therapy pumps and training will be provided free of charge
- Decellularised dermal allograft and training will be provided free of charge
- A camera and equipment will be provided free of charge
- Wound tracing grids and pens will be provided free of charge
- Per patient payments: £375 per randomisation, £39 per patient for travel/parking costs
- Disposable items: **The Trust will not incur any excess treatment costs.** Centres are required to apply to the CCG in the first instance, if the CCG will not support the costs then the costs can be claimed back from NHS Blood and Transplant who are underwriting the study. Trusts will order the disposables through the usual ordering process and claim the money back from NHSBT by invoice.