1 Figures

Figure 1 - Trial Flow Diagram

Identification of patients and completion of screening log

Full informed consent

Formal screening to meet inclusion criteria

Baseline assessments:
1) Baseline Questionnaires (Q1):
   - Foot pain, The Foot Function Index (FFI) pain subscale
   - Physical function, Scleroderma Health Assessment Questionnaire (S-HAQ)
   - Manchester Foot Pain and Disability Questionnaire (MFPDQ)
   - Scleroderma Quality of Life (SSc QOL)
   - Foot Pain Map (Baseline only)
2) The modified Rodnan skin score (MRSS)

Randomisation 140 patients randomised on a one to one basis using the 24-hour automated randomisation system based at the CTRU

a) Intervention insole (commercially available insole (Algeos Duosoft therapeutic®))
b) Sham insole (with a similar appearance to the active intervention)

Leeds centre only (exploratory measures of foot plantar pressures) carried out at baseline on patients providing additional consent for this procedure:
   - Bare foot plantar pressures (measured by EMED-ST pressure platform (hi-res))
   - In-shoe plantar pressures (measured by Novel Pedar System)

Telephone follow-up at 6 weeks post randomisation

12 Week follow-up assessments:
12 week Follow-up Questionnaires Q2:
   - Foot pain, The Foot Function Index (FFI) pain subscale
   - Physical function, Scleroderma Health Assessment Questionnaire (S-HAQ)
   - Manchester Foot Pain and Disability Questionnaire (MFPDQ)
   - Scleroderma Quality of Life (SSc QOL)