



Eligible patients

Baseline assessments
Clinical assessments: - Digital photo of reference ulcer and tracing.
Record of : VAS Pain Score, current medication, medical history, standard care administered (if any), demographic data, contact details for patient and their GP.

Randomisation – to placebo/aspirin
IMP to be collected by patient on next visit to clinic or posted direct to patient.

Reference ulcer judged as healed
Participant to continue with trial medication

1 week after judged as healed
Healing outcomes – Digital photo of reference ulcer and date taken
Treatment concordance
Adverse events
Change to standard care administered/types of dressings.

Weekly assessments for 25 weeks post-randomisation
Healing outcomes – Digital photo of reference ulcer and date taken.
Record of: Treatment concordance (including initially, date trial treatment commenced), adverse events/changes in medical condition, changes to other medication, change in type of dressings used.

5 weeks post-randomisation
In addition to weekly assessments, participants will be asked about ulcer related pain (VAS pain score).

2 weeks after judged as healed
Healing outcomes – Digital photo of reference ulcer and date taken, and clinical assessment of photo.
Treatment concordance.
Adverse events
Change to standard care administered/types of dressings

25 weeks post-randomisation: Final assessment of patients whose leg ulcers have been confirmed as healed on or before week 25, or whose leg ulcers are not suspected as healed.
In addition to weekly assessments, there will be a grid tracing of reference ulcer.
IMP container and remaining medication returned for all trial participants.

Healed
Participant given a card and ask to notify the trial team if wound breaks down.
Discontinues trial medication and remaining medication returned to St Geroge’s Research Pharmacy.

Not Healed
Participant continues with trial medication and continues in trial

26 weeks post-randomisation (Only patients whose leg ulcers were suspected as healed in weeks 24 and/or 25.)
Digital photo taken of wound area.
Record of adverse events, changes to other medication and change in type of standard care administered.
(For patients whose leg ulcer was suspected as healed in week 24, an assessment will be made of digital photo to confirm healing.)

27 weeks post-randomisation (Only patients whose leg ulcers were suspected as healed in week 25)
Digital photo taken of wound area.
Record of adverse events, changes to other medication and change to standard care administered/types of dressings
(Assessment of digital photo to confirm healing).

25 weeks post-randomisation
Research nurse phones patient to ask if ulcer has recurred and collect adverse event data