Evaluation of glyceryl trinitrate ointment as treatment for leg ulcers

ACTRN12616000520437

Status	RECRUITING
Phase	Phase 2
Sponsor	The Prince Charles Hospital
Enrollment	40 participants

Plain Language Summary

This study is testing whether a medicated ointment containing glyceryl trinitrate (GTN) — the same ingredient found in some heart medications — can help heal venous leg ulcers when applied directly to the wound. GTN releases nitric oxide, which improves blood flow and may kill harmful bacteria. Half of patients will receive the real GTN ointment and half will receive a look-alike placebo ointment, and neither the patients nor the nurses treating them will know which one is which.

You may be eligible if:
- You are 45 years or older
- You have been admitted to hospital with a venous leg ulcer (confirmed by your medical team)
- Your ulcer is not caused by arterial disease, pressure, or diabetes

You may NOT be eligible if:
- Your ulcer is a malignant (cancer-related) ulcer
- You have any type of active cancer
- You have an active autoimmune disease or have had an organ transplant
- You are having a sudden, severe worsening of heart disease (acute cardiac exacerbation)

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (3)

- transdermal oxygen sensors will not be used. Clinical judgement will be used.
- This investigation seeks to recruit consenting patients with venous leg ulceration from the internal medicine wards of the Prince Charles Hospital (TPCH). Venous ulceration will be confirmed by clinical judgement and patient notes and/or confirmation by medical and/or podiatry team. This is to rule out ulceration by other aetiologies (i.e. arterial, pressure, diabetic) which have been shown in earlier studies to not benefit from GTN application (data not published).
- Patients recruited into this study will be informed that their participation in this trial is entirely voluntary and no financial payment will be given. If patients decide to not take part in this study, there will be no prejudice against their future care and are free to withdraw at any time. Consenting patients will then be randomly allocated to one of two groups (placebo versus GTN treatment).

Exclusion (1)

- Patients must have venous ulceration. Additionally, patients with malignant ulcers or have other forms of malignancy will be excluded from the study together with any patient who has active autoimmune disease or have had organ transplantation. Patients with acute exacerbation of cardiac disease may be excluded from treatment with GTN as the product may lower blood pressure. Those with ongoing / active cardiac disease will be included.

Locations (1 total)

The Prince Charles Hospital - Chermside, QLD, Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12616000520437