Venous Ulcer Studies at YTU

VenUS I to IV – all HTA funded
VenUS I

- Began 1998; published 2004
- HTA funded (£378,388)
- 4-layer vs. short stretch bandaging
- Economic evaluation
- 387 participants
VenUS I: what did we learn?

• 4-layer bandage heals ulcers more quickly than SSB and is cost-effective
• The importance of enthusiastic community nurses
• Next time we should do blinded outcome assessment ...
VenUS II: the revenge of the maggot
VenUS II

• Began 2003; published 2009
• £1.1 million
• People with venous ulcers randomised to three groups:
  – loose larvae,
  – bagged larvae,
  – standard hydrogel treatment
• Treatments applied only during debridement.
• 267 participants
• Masked assessment of endpoint (photographs)
A lot to contend with ....

- CTIMP just as EU Clinical Trials Directive came into force
- Larval therapy supplier sought to influence trial design and threatened us with legal action
- ... and published an illegal advert
For rapid cost-effective wound debridement, one product leads the field* ...........

Now available on prescription!

LarvE® Developed by the NHS for the NHS

LarvE®, sterile maggots of Lucilia sericata, are produced by the Biosurgical Research Unit, Princess of Wales Hospital, Cottit Road, Bridgend CF31 1BQ.

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Venus II: Time to a Clean Wound

![Graph showing time to a clean wound for different treatments: Loose larvae, Bagged larvae, and Hydrogel.](image_url)
VenUS II: Time to Healing

The graph shows the proportion of healed cases over time for three different treatment methods:
- **Loose larvae** (red dashed line)
- **Bagged larvae** (blue dotted line)
- **Hydrogel** (green solid line)

The x-axis represents time in days, ranging from 0 to 400. The y-axis represents the proportion healed, ranging from 0.00 to 1.00. The graph illustrates the comparative effectiveness of each method in promoting healing over time.
Larval therapy for leg ulcers (VenUS II): randomised controlled trial

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VenUS IV Bandages vs. Stockings

- Compression bandaging vs. two layer compression hosiery
- £1,034,528
- 457 participants randomised
- Hosiery more cost effective than bandages
VenUS IV – so much more than a trial

• RCT plus within-trial economic evaluation
• Mixed treatment comparison meta-analysis putting the new evidence in the context of all existing evidence
• Decision analytical modeling for cost effectiveness relative to alternatives
• Value of information analysis
  – 2 layer bandage had highest probability of being most cost-effective but low quality evidence (high uncertainty)
  – VOI also indicated RCT of 2 layer bandage would be good use of resources – unfortunately NIHR HTA did not agree
What YTU Means to Me

• Rigour plus pragmatism
• Complex interventions
• Methodological research alongside high quality trials
• Excellent trial managers
• Economic evaluations
• Feels like collaborative research and not a service
HAPPY BIRTHDAY

YTU