

VenUS II: larval therapy Venous Ulcer Study

Submission date 18/06/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 18/06/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/02/2010	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

HTA 01/41/04

Study information

Scientific Title

Acronym

Study objectives

Non-healing leg ulcers are common, costly to the NHS and distressing for patients. Many leg ulcers contain slough and necrotic tissue and, whilst removal of these tissues (debridement) is widely thought to contribute to healing, direct evidence is lacking. Larval therapy has been proposed as a quick and effective debridement strategy and is increasingly used in the NHS, mainly by nurses. Larval therapy may achieve debridement more swiftly than modern wound dressings, which promote a moist environment aiding self debridement, and, unlike surgical debridement, larval therapy use is not reliant on highly trained personnel or the fitness of the patient for surgery. A further benefit of larval therapy, namely the removal of wound bacteria and Methicillin-Resistant Staphylococcus Aureas (MRSA) in particular, has been suggested, but robust evidence of this is also required. This study will establish the cost-effectiveness of larval therapy in the healing of venous and mixed arterial/venous leg ulcers; it will also assess the impact of larval therapy on wound microbiology, including MRSA, and the acceptability of the treatment for patients.

Please note that, as of 16 January 2008, the anticipated end date of this trial has been updated from 30 June 2007 to 30 April 2008.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Venous and mixed aetiology leg ulcers

Interventions

3 armed trial: Larval therapy (loose and bagged) and Purilon hydrogel

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Added 10/07/08:

Time to healing of reference ulcer

Key secondary outcome(s)

Added 10/07/08:

1. Time to debridement of reference ulcer
2. Health related quality of life
3. Bacterial load (including MRSA)
4. Adverse event data
5. Costs of leg ulcer treatments

Completion date

30/04/2008

Eligibility**Key inclusion criteria**

Adults over 18 years old with leg ulcers containing slough and/or necrotic tissue

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Does not comply with inclusion criteria

Date of first enrolment

01/09/2003

Date of final enrolment

30/04/2008

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Dept of Health Sciences
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

ROR
<https://ror.org/04m01e293>

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	cost-effectiveness results	19/03/2009		Yes	No
Results article	results	19/03/2009		Yes	No
Other publications	HTA report	01/11/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes