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VenUS II: larval therapy Venous Ulcer Study

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.york.ac.uk/healthsciences/centres/trials/larthe.htm

Contact information

Type(s)
Scientific

Contact name
Prof Nicky Cullum

Contact details
Dept of Health Sciences
SRB (Area 2)
University of York
Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904 321343
nac2@york.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 01/41/04

Study information

Scientific Title

Acronym
VenUS II

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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Added 10/07/08:
Time to healing of reference ulcer

Secondary outcome measures
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

Overall study start date
01/09/2003

Completion date
30/04/2008

Eligibility

Key inclusion criteria
Adults over 18 years old with leg uclers containing slough and/or necrotic tissue

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Added 10/07/08: 370 patients

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
England

United Kingdom

Study participating centre
Dept of Health Sciences
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

Sponsor details
Heslington
York
England
United Kingdom
YO10 5DD

Sponsor type
University/education

Website
http://www.york.ac.uk/

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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