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A study to assess the efficacy of maggots as a wound debridement agent for venous leg ulcers under graduated compression bandages

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 19/08/2015	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0106142799; MT4VLU07/A-V5

Study information

Scientific Title
A study to assess the efficacy of maggots as a wound debridement agent for venous leg ulcers under graduated compression bandages

Study objectives
Current hypothesis as of 04/09/2007:
To determine whether or not maggots are able to survive under layers of compression bandages and whether they provide a clinically beneficial debridement therapy for sloughy venous leg ulcers.

Previous hypothesis:
To determine whether or not maggots are able to survive under layers of compression bandages and whether they provide a clinically beneficial and cost effectiveness therapy for sloughy venous leg ulcers.

Please note that as of 04/09/2007 this trial record was amended. The main reason for these changes are due to the change in the classification of maggots (now classified as an investigational medicinal product), and therefore MHRA approval was to be sought. Before this could be performed, however, a licence number for the investigational medicinal product was to be provided and this, at the time, did not exist. However, the maggots used in this trial do now have a licence number and therefore ethics re-approval and MHRA approval are being sought, and this trial will go ahead as planned.

The original overall trial start and end dates were as follows:
Overall trial start date: 05/04/2004
Overall trial end date: 06/04/2004

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending from Southmead Research Ethics Committee as of 04/09/2007

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Venous ulcers

Interventions
1. Control group: compression bandages
2. Treatment group: compression bandages and maggots

Intervention Type
Other

Primary outcome measure
Current primary outcome measures as of 04/09/2007:
Percentage area debridement following maggot treatment, compared to standard treatment.

Previous primary outcome measures:
Maggot survival and reduction in time to heal venous leg ulcers.

Secondary outcome measures
Current secondary outcome measures:
Time to healing (in weeks)

Please note that previous to this addition there were no secondary outcome measures.

Overall study start date
03/12/2007

Completion date
02/06/2008

Eligibility

Key inclusion criteria
Inclusion criteria as of 04/09/2007:
1. Patient is at least 18 years of age
2. Ankle Brachial Pressure Index greater than or equal to 0.85. N.B. calculations to be made using Doppler ultrasound measurements from both dorsalis pedis and posterior tibial arteries to minimise error (standard procedure)
3. Patient has a venous leg ulcer, located between the knee and ankle (at the level of, and including, the lateral and medial malleoli). The ulcer must be confirmed as of venous origin by venous duplex ultrasound
4. Patient's ulcer is a minimum of 4 cm^2 and a maximum of 100 cm^2 on initial screening
5. Patient's ulcer is covered by a minimum of 20% slough calculated using the manual and computer-aided planimetry method)
6. Patient understands and is willing to participate in the clinical study and can comply with the follow-up regime
7. Patient has read the patient information leaflet and signed the Local Research Ethics

Committee approved informed consent form before screening and commencement of trial treatment

Previous inclusion criteria:
40 subjects aged over 18 with a venous ulcer

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
40 (20 in control group + 20 in treatment group)

Key exclusion criteria
Exclusion criteria as of 04/09/2007:
1. Patient's ulcer should not show exposed blood vessels, tendon, muscle or bone
2. Patients with a history of a bleeding disorder that, in the opinion of the researcher, would make compliance with the trial protocol medically unsafe
3. Patients who are unable to understand the aims and objectives of the trial
4. Patient has any condition(s), which seriously compromises the patient's ability to complete this study, or has a known history of poor compliance with medical treatment
5. Patient has an aversion to maggots, despite careful and informative discussion between researcher and patient and explanation of the benefits of maggots

Please note that previous to this addition there were no exclusion criteria.

Date of first enrolment
03/12/2007

Date of final enrolment
02/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Cheltenham General Hospital
Cheltenham
United Kingdom
GL53 7AN

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Gloucestershire R&D Consortium (UK)

Funder Name
Vascular Department, Cheltenham General Hospital (UK)

Funder Name
NHS R&D Support Funding (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	results	01/12/2015		Yes	No