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Community Treatment of Venous Ulcers with Concomitant Use of Compression Pump and V.A.C. Suction Therapy - A Novel Approach

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 21/04/2015	**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
N0388170252

Study information

Scientific Title
Community Treatment of Venous Ulcers with Concomitant Use of Compression Pump and V.A.C. Suction Therapy - A Novel Approach

Study objectives
Does the use of compression pump and suction therapy provide better management for venous ulcers than the standard 4 layer bandages being used?

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)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Compression pump and suction therapy versus standard 4 layer bandages

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Complete healing of venous ulcers

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/02/2005

Completion date
05/03/2007

Eligibility

Key inclusion criteria
1. Patients with chronic venous ulcer with an area of >25 sq cm
2. Aged between 18 and 80 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Patients <18 years of age and >80 years of age
2. Patients likely to be pregnant
3. Patients who are immobile
4. Patients with peripheral vascular disease with ankle brachial pressure index (ABPI) <0.6 non-diabetics, <0.8 diabetics
5. Patients with recent deep vein thrombosis (DVT), congestive cardiac failure or disabling stroke
6. patients with concurrent terminal disease with an expected lifespan <1 year

Date of first enrolment
02/02/2005

Date of final enrolment
05/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Hillingdon Hospital NHS Trust
Uxbridge
United Kingdom
UB8 3NN

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
79 Whitehall
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SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Hillingdon Hospital NHS Trust (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