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Extracorporeal Shock Wave Therapy (ESWT) in the management of Decubitus ulceration in complex neurological disabilities

Submission date	Recruitment status	[_] Prospectively registered
28/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/04/2010	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0204185326

Study information

Scientific Title

Study objectives
To assess whether ESWT improve the rate of healing of decubitus ulceration in people with complex neurological disabilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single blind crossover study

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
Skin and Connective Tissue Diseases: Decubitus ulceration

Interventions
The radiographer will be aware of the treatment (ESWT or placebo) and it is likely that the patient may sense some difference between treatments. The Research Nurse carrying out the measurements will be blind to the treatment.
The patient will either receive one dose of Shockwave therapy or placebo each week for four weeks then after two weeks wash out period the other treatment will be delivered, one dose each week for four weeks..

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
The primary outcome will be the area of pressure sore healed by the end of one month period.

Secondary outcome measures
1. Time to heal 50%
2. Time to complete healing
3. Site of ulceration

Overall study start date
01/10/2006

Completion date
30/09/2007

Eligibility

Key inclusion criteria
All patients in the Royal Hospital for Neuro-disability with decubitus ulceration who do not have exclusion criteria will be included in the study irrespective of age, level of disability or diagnosis. The total number of patients at the Royal Hospital available for the study is expected to be 36.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
36

Key exclusion criteria
1. Those patients who decline to receive treatment after the treatment has been explained to them
2. Those with bleeding disorders or who are on anticoagulant therapy
3. Decubitus ulceration of the chest wall (theoretical risk of lung damage from ESWT)
4. Decubitus ulceration of elbows and elbow creases (uncommon and difficult to access)
5. Ulceration of the ear (uncommon, difficult to access, risk of damage to brain)
6. Over a tumor site

Date of first enrolment
01/10/2006

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Neuropalliative Rehabilitation
London
United Kingdom
SW15 3SW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
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
Royal Hospital for Neuro-disability

Funder Name
NHS R&D Support Funding

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	01/03/2010		Yes	No