

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

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/04/2010	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**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

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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?
<a href="#">Results article</a>	results	01/03/2010		Yes	No