

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

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/04/2010	Condition category 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

Protocol serial number
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

Primary study design

Interventional

Study design

Single blind crossover study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

Royal Hospital for Neuro-disability

Funder Name

NHS R&D Support Funding

Results and Publications

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