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A feasibility study and open pilot two-arm randomised controlled trial comparing Pressure Garment Therapy with no Pressure Garment Therapy for the prevention of abnormal scarring after burn injury

Submission date
03/10/2014

Recruitment status
No longer recruiting

Registration date
03/10/2014

Overall study status
Completed

Last Edited
28/06/2018

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Pressure garments are tightly fitting pieces of Lycra-based clothing which apply a constant pressure directly on the skin. They are used for patients who have had burn injuries and are worn day and night for about 12 months after the actual burn wound has healed. Wearing these garments may reduce the potential complications of scarring while providing comfort and helping to improve symptoms such as itch, which can be very distressing for patients recovering from burns. However, there is little evidence to confirm this and there is a lack of information about the costs of the garments and the staff time required to provide this treatment. There are also costs to patients, parents and carers which can include discomfort and possible damage to the skin, and the inconvenience of having to attend frequent outpatient clinic appointments to have the garments fitted. It can be challenging to keep going with the pressure therapy and some patients find it too difficult to stay the course. In order to run a large study of the clinical and cost effectiveness of pressure garment therapy, we first need to have more information about the patients and healthcare professionals who might participate, and identify possible barriers and measurement problems.

Who can participate?
Adults and children with burn injuries

What does the study involve?
First, we investigate the current practice of using pressure garments. We carry out a survey to find out numbers of patients using pressure garments and what other scar management strategies are being used. Secondly we gather background information including the views and perspectives of staff in specialist burns units in the UK. We are particularly interested in their willingness to recruit participants and their views on important outcomes for patients. Thirdly, we are keen to understand patient or carer views on a study where patients would be randomly

allocated to use or not use pressure garments, and to identify outcomes that are important to them, both in the short and long term. We then design a pilot study to compare patients using or not using pressure garments. The patients invited to take part are those who, in current circumstances, would be offered pressure garments. This helps us to assess how willing healthcare professionals are to ask their patients to participate in such a study, and the willingness of patients to be recruited and to carry out the treatment as prescribed. Both recruitment and adherence to treatment are vital to produce results that are reliable and valid. Assessments of costs and benefits are also undertaken during this phase. The pilot study should provide a good indication of any changes that are needed if a larger study is to be undertaken in the future. In order to identify any issues that could interfere with running a full study, we carry out an evaluation of the process of setting up and participating in this pilot study. This involves interviews with healthcare professionals, participants and non-participants to provide us with insights into any difficulties encountered. Patients are reviewed over the course of 12 months. It is already known that compliance with pressure garment treatment can be variable, and during this phase of the study both patient diaries and questionnaires are used to help identify the most accurate method of measuring treatment adherence.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Birmingham Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
October 2014 to June 2015

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
17346; 12/145/04

Study information

Scientific Title
A feasibility study and open pilot two-arm randomised controlled trial comparing Pressure Garment Therapy with no Pressure Garment Therapy for the prevention of abnormal scarring after burn injury (PEGASUS)

Acronym
The PEGASUS Trial - Comparing PGT with no-PGT

Study objectives
Recovery from a burn injury is a long process, involving a number of physical and psychological challenges for patients. Scarring and the appearance of scars are important concerns for patients. Pressure garment therapy (PGT) has become the treatment of choice to control abnormal scarring of the damaged skin and has been used routinely since the 1970s. However, its effectiveness has been difficult to measure. The overall aim of the proposed study is to find out how likely it is that we can design and conduct a large clinical trial to assess whether patients treated with PGT to have better outcomes, such as reduced scarring, or reduce the time to maturation compared to burns patients that do not use PGT.

The study will be carried out in two phases P1 and P2.

In Phase 1: Firstly, we will investigate current practice of using PGT. We will carry out a survey to establish the number of patients receiving pressure garment therapy, what protocols for scar management are being used, and what other scar management strategies are employed. Secondly, we will explore views and perspectives regarding an RCT of pressure garment therapy from staff in specialist burns units in the UK. Thirdly, we will explore patient (adults and children) and carer views on a trial where patients would be randomised to pressure garment therapy or no pressure garment therapy and to identify outcomes that are important to them, both in the short and long term.

In Phase 2: A pilot trial informed by Phase 1 will compare pressure garment therapy versus no pressure garment therapy in adults and children recovering from burn injuries. A qualitative process evaluation will run alongside this trial.

Further details can be found at: http://www.nets.nihr.ac.uk/projects/hta/1214504

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Coventry & Warwickshire Research Ethics Committee, 08/07/2014, ref: 14/WM /0160

Primary study design

Interventional

Study design
Randomised; Interventional and Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Children, Injuries and emergencies; Subtopic: All Diagnoses, Injuries and Emergencies (all Subtopics); Disease: Injuries and Emergencies, All Diseases

Interventions
Patients are randomised to the following:
1. No Pressure Garment Therapy: No Pressure Garment Therapy, patient will receive other scar management therapies - silicone, moisturisation, massage
2. Pressure Garment Therapy, Pressure Garment Therapy in addition to other scar management therapies - silicone, moisturisation, massage
Follow Up Length: 12 month(s)

Intervention Type
Procedure/Surgery

Primary outcome(s)
Can a large national RCT looking at PGT vs. no PGT be delivered successfully? Timepoint(s): 12 months

Key secondary outcome(s)
1. Health economics; Timepoint(s): 12 months
2. Pain and itch; Timepoint(s): 12 months
3. Patient reported outcomes; Timepoint(s): 12 months
4. Validated scar measurement outcomes; Timepoint(s): 12 months

Completion date
30/06/2015

Eligibility

Key inclusion criteria
Patients who will be considered eligible for inclusion include:
1. Adults and children (age > 0 years) with burn injuries greater than 1 % Total Body Surface Area
2. Treated with split thickness skin grafts
3. Or conservatively managed burn wounds or donor sites which have taken > 2 weeks to heal
4. Evidence of hypertrophic scarring
5. Considered suitable for Scar Management Therapy; Target Gender: Male & Female

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
All

Sex
All

Key exclusion criteria
1. Since Patient Reported Outcomes (PROs) identified from P1 may not be available in translated versions the pilot work will exclude participants who cannot speak, read and write in English
2. Significant psychiatric history
3. Deliberate self harm
4. Preexisting skin conditions affecting wound healing
5. History of keloid scarring
6. Known allergy to Pressure Garment Therapy (Lycra)

Date of first enrolment
01/10/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Clinical Trials Unit
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust (UK)

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme; Grant Codes: 12/145/04

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results from HCP attitudes survey	01/12/2015		Yes	No
Results article	results on patient-reported outcome measures	01/12/2017		Yes	No
Results article	results from parent survey	01/05/2018		Yes	No
Results article	results	01/06/2018		Yes	No
HRA research summary			28/06/2023	No	No