

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 28/06/2018	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> 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?
Gemma Slinn
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised; Interventional and Observational

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2014

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

Age group

All

Sex

Both

Target number of participants

Planned Sample Size: 88; UK Sample Size: 88

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

England

United Kingdom

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

Sponsor information

Organisation

University Hospital Birmingham NHS Foundation Trust (UK)

Sponsor details

Department of Primary Care & General Practice
Room 140
Primary Care Clinical Science Building
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type

Hospital/treatment centre

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, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

01/12/2016

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 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