Welcome to the third issue of the PEGASUS Newsletter!

Welcome to the third PEGASUS newsletter. We’d like to start with a massive thank you to our seven centres in the pilot trial. PEGASUS reached its recruitment target of 88 patients on the 19th of August! The qualitative team are continuing their work interviewing patients, but we can now present you with some of their initial findings from the staff survey.
Message from the Chief Investigator

Dear Colleagues,

I am delighted that we have reached our recruitment target for PEGASUS and I thank you for all of your commitment and hard work. There are challenges to ensure that we retain the patients for the full length of the trial but I am sure we can all work together to overcome these. The PEGASUS Study Team is always happy to assist with any issues (contact details can be found at the end of this newsletter) so please don’t hesitate to get in touch us.

It was fantastic to see so many of you at the Investigators Meeting last week and I hope to see as many of you as possible at our final Investigators Meeting on Thursday 9th June 2016.

Thank you for your continued support of this very important study.

Best wishes,
Mr Naiem Moiemen

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Trial Design

Open pilot 2-arm feasibility Randomised Controlled Trial

Aims

The overarching aim of the project is to define the design and assess the feasibility of a full-scale open trial of the effectiveness and cost-effectiveness of pressure garments. The aim is addressed through two interlinked Phases (P1 and P2) of feasibility work. Refer to the protocol for the full aims.

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
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<tr>
<td>- Adults and Children with burn injuries ≥ 1 % Total Body Surface Area</td>
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<tr>
<td>- Those treated with split thickness skin grafts or conservatively managed burn wounds or donor sites which have taken &gt; 2 weeks to heal</td>
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<td>- Those with potential for hypertrophic scarring</td>
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<td>- Those considered suitable for Scar Management Therapy</td>
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<tr>
<td>- Cannot read, write or understand English. Since the outcomes identified from P1 may not have data collection tools in translatable versions for the future RCT, patient’s understanding of English is essential.</td>
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<td>- Have pre-existing skin conditions affecting wound healing</td>
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<td>- Have a history of keloid scarring</td>
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<td>- Have a known allergy to Lycra or any other component of pressure garments</td>
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<tr>
<td>- Are not, in the investigator’s opinion, suitable to participate in the trial due to clinically relevant past medical history or other pertinent factors.</td>
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Pilot Trial Updates

Recruitment

A massive thank you to our seven RCT sites on reaching the target of 88 patients on 19th August. This is a fantastic achievement and is an important step as we start to look forward to a full PEGASUS trial.

Retention

The hard work doesn’t stop with recruitment, the retention of patients in the PEGASUS trial is also a key outcome. Please continue to follow up patients per protocol until the study closes on 31st May 2016.

Crossover – If patients switch trial arm because there is a clinical need or the patient wishes to withdraw from their randomised treatment, we would ask that where possible that you still follow up these patients as per the protocol. As long as the patient is happy to continue this does not count as a withdrawal from the trial.

Lost to follow up – If a PEGASUS patient has missed a follow up time point but later comes back for a clinic appointment then, if the patient is happy to continue in the trial, we would still like to receive their follow up data. The new visit should be documented against the closest follow up time point in the protocol.

Goodbye to Dana and welcome to Dawn

As you probably know by now, we said goodbye to the PEGASUS Trial Coordinator, Dana in May. Dana left us for the far sunnier climes of Adelaide in Australia. I’m sure you’ll agree that Dana did a fantastic job helping to get the study to the stage it’s at now. We wish her the very best for the future.

October sees us welcome a new Trial Co-ordinator to the PEGASUS team. Many of you met Dawn Brant at the Investigators Meeting last week and over the coming months I’m sure you’ll be in frequent contact with her as the trial continues.

Housekeeping – clean away the cobwebs!

There have been many updates to trial documentation including the protocol, patient documentation and CRFs so can we ask that you take the time to ensure that all of your documents are up-to-date with previous versions marked as superseded and filed in your Investigator Site Files.

Likewise, please can you ensure that your delegation logs are kept up-to-date (this includes crossing out members of staff who no longer work on the trial).
**Qualitative Work Updates**

**Key findings from the staff survey**

**Considerations for a full-scale RCT**

- Responses from the staff survey will need to be considered when designing a full-scale RCT, including views on:
  - Recruitment
  - Retention
  - Compliance
  - Outcome measures

- When asked if they would be willing to participate in a full-scale RCT nearly two thirds of respondents answered yes.

**Basis for this conclusion?**

Responses to the staff survey were received from 28 of the 30 burns services across England, Scotland and Wales.

- There are subtle differences in views expressed by staff in the pilot sites and those in the non-pilot sites:
  - Those in the non-pilot sites have slightly stronger views in favour of PGT although this is difficult to explain.

Therefore any issues observed in PEGASUS are likely to be relevant in a full-scale trial to all burns services beyond the pilot trial sample.

**What are these doubts?**

- Patients’ understanding of the trial and evidence for PGT i.e. information provision
- Participation of patients and especially children & parents
- Staff’s understanding of the trial and evidence for PGT i.e. how they deal with equipoise
- Accommodating the trial into busy clinical practice
- Estimates of time and resource needed by staff to participate in a trial
- Patient and clinical perspectives on the appropriateness of scar and other assessments (outcomes)
# PEGASUS Study Details

<table>
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<tr>
<th>Sponsor:</th>
<th>Funding:</th>
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<tr>
<td>University Hospitals Birmingham NHS Foundation Trust</td>
<td>HTA</td>
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REC ref. no.: 14/WM/0160

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### Dates for your diary:
- **BCTU closed:** 23rd December 2015 - 3rd January 2016
- **Study close date:** 31st May 2016
- **Investigators Meeting:** Thursday 9th June 2016

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Thank you for taking the time to read the PEGASUS Newsletter!