

# Leucopatch in the management of hard to heal diabetic foot ulcers

<b>Submission date</b> 05/07/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/07/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/09/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<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

**Contact name**  
Mrs Eleanor Harrison

**Contact details**  
Nottingham Clinical Trials Unit  
University of Nottingham  
Queens Medical Centre  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH  
-  
leucopatch@nottingham.ac.uk

## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT02224742

**Protocol serial number**  
14626

## Study information

**Scientific Title**

Leucopatch in the management of hard to heal diabetic foot ulcers: a randomised controlled trial

**Acronym**

DRN 819 Leucopatch II

**Study objectives**

Diabetic foot ulcers are the source of considerable suffering and cost and there are currently no wound care products available that have been demonstrated to improve healing, or that are cost effective. There have however been a small number of studies which have examined the use of platelets or fluid derived from platelets, either from the patients own blood or from blood bank products. These have suggested some promise, but have suffered from technical difficulties in making a suitable wound care product or the volume of blood required to derive the product. It is thought that the reason why they may work is that growth factors released by the platelets may stimulate the wound to heal.

This study will be a formal, randomised controlled trial to assess a new device for creating a wound care product which is a plug or patch comprising fibrin, white cells and platelets derived from 18 mls of the patients own blood. The application of this fibrin/white cell/platelet patch to the patients wound on a weekly basis will be compared with usual best care in patients with hard to heal Diabetic Foot Ulcers in a secondary care setting in 25 centres in the UK, Denmark and Sweden.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

13/WM/0202; First MREC approval date 24/05/2013

**Primary study design**

Interventional

**Study design**

Randomised; Interventional; Design type: Treatment

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Topic: Diabetes Research Network; Subtopic: Both; Disease: Diabetic foot

**Interventions**

Leucopatch, topical application of a fibrin/white cell/platelet patch prepared by the Leucopatch device

Study Entry : Registration and One or More Randomisations

**Intervention Type**

Device

**Primary outcome(s)**

Ulcer healing; Timepoint(s): 20 weeks after randomisation

### **Key secondary outcome(s)**

Added 05/01/2017:

Ulcer-related outcomes:

1. Time (days) to healing in those that heal by 20 weeks
2. The incidence of healing within 12 and 26 weeks
3. Change in ulcer area at 4, 12, 16, 20 and 26 weeks
4. Change in ulcer healing rate between the run-in-period and the first four weeks in the treatment period
5. The incidence of secondary infection
6. Number of days of systemic antibiotic therapy administered for infection of foot ulcer during the 20 weeks from randomisation
7. Durability of wound healing 12 weeks after complete wound healing

Patient-related outcomes:

1. The incidence of major (above ankle) amputation affecting the target limb by 12, 20 and 26 weeks
2. The incidence of major amputation affecting the contralateral limb by 26 weeks
3. The incidence of minor (below ankle) amputation affecting the target limb by 12, 20 and 26 weeks
4. The incidence of minor amputation affecting the contralateral limb
5. Quality-of-life measured using SF-12 and EQ-5D at baseline, 12 and 20 weeks
6. Pain measured by VAS
7. Incidence of new anaemia

Health economic analysis:

1. Cost effectiveness and cost utility

### **Completion date**

31/05/2018

## **Eligibility**

### **Key inclusion criteria**

1. People aged 18 years and over who have diabetes complicated by one or more ulcers on a foot or both feet below the level of the malleoli, excluding ulcers confined to the interdigital cleft
2. Those with more than one eligible ulcer will have one usually the largest or more clinically significant selected at screening as the index ulcer
3. Eligible ulcers will be hard-to-heal, meaning that the cross-sectional area will decrease by less than 50 % during a four week run-in period
4. HbA1c  $\leq$  108 mmol/mol at screening
5. The cross-sectional area of the index ulcer will be between  $\geq$ 50 and  $\leq$ 1000 mm<sup>2</sup> at the end of the 4 week run-in period
6. At randomisation, the index ulcer will be clinically non-infected according to IDSA criteria
7. Either the ankle-brachial index (ABPI) in the affected limb will be between 0.50 and 1.40 or the dorsalis pedis pulse and/or tibialis posterior pulse will be palpable
8. Participants will have the capacity to understand study procedures, and will be able to provide written informed consent

Target Gender: Male & Female ; Lower Age Limit 18 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Key exclusion criteria**

Current exclusion criteria as of 05/01/2017:

1. Haemoglobin concentration <105 g/L or 6.5 mmol/L at screening
2. Presence of sickle-cell anaemia, haemophilia, thrombocytopenia (<100x10<sup>9</sup>/L) or other clinically significant blood dyscrasia
3. Known potential infectivity of blood products, including known HIV and hepatitis
4. Dialysis or an estimated GFR (based on cystatine C or serum creatinine) <20 ml/min/1.73m<sup>2</sup>
5. Increase in cross-sectional area of the index ulcer by ≥25% during the 4 week run-in period, or is either smaller than 50 mm<sup>2</sup> or larger than 1000 mm<sup>2</sup> at the end of that time
6. Clinical signs of infection of the index ulcer or reason to suspect that infection is present at randomisation.
7. Revascularisation procedure in the affected limb planned, or undertaken within the 4 weeks prior to screening
8. Current treatment with cytotoxic drugs or with systemically administered glucocorticoids or other immunosuppressants.
9. Treatment of foot ulcers with growth factors, stem cells or equivalent preparation within the 8 weeks prior to screening
10. The need for continued use of negative pressure wound therapy
11. Likely inability to comply with the need for weekly visits because of planned activity
12. Participation in another interventional clinical foot ulcer-healing trial within the 4 weeks prior to screening
13. Prior randomisation in this trial
14. Judgement by the investigator that the patient does not have the capacity to understand the study procedures or provide written informed consent

Previous exclusion criteria:

1. Haemoglobin concentration <105 g/L or 6.5 mmol/L at screening
2. Presence of sickle-cell anaemia, haemophilia, thrombocytopenia (<100x10<sup>9</sup>/L) or other clinically significant blood dyscrasia
3. Known potential infectivity of blood products, including known HIV and hepatitis
4. Dialysis or an estimated GFR (based on cystatine C or serum creatinine) <20 ml/min/1.73m<sup>2</sup>
5. Increase in cross-sectional area of the index ulcer by ≥25% during the 4 week run-in period, or is either smaller than 50 mm<sup>2</sup> or larger than 1000 mm<sup>2</sup> at the end of that time
6. Revascularisation procedure in the affected limb planned, or undertaken within the 4 weeks prior to screening

7. Current treatment with cytotoxic drugs or with systemically administered glucocorticoids
8. Treatment of foot ulcers with growth factors, stem cells or equivalent preparation within the 8 weeks prior to screening
9. Likely inability to comply with the need for weekly visits because of planned activity
10. Participation in another interventional clinical foot ulcer-healing trial within the 4 weeks prior to screening
11. Prior enrolment in this trial
12. Judgement by the investigator that the patient does not have the capacity to understand the study procedures or provide written informed consent

**Date of first enrolment**

15/07/2013

**Date of final enrolment**

31/05/2017

## Locations

**Countries of recruitment**

United Kingdom

England

Denmark

Sweden

**Study participating centre****Clinical Trials Unit**

Nottingham

United Kingdom

NG7 2UH

## Sponsor information

**Organisation**

Nottingham University Hospitals NHS Trust (UK)

**ROR**

<https://ror.org/05y3qh794>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Reaplix (Denmark)

## 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?
<a href="#">Results article</a>	results	01/11/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes