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Leucopatch in the management of hard to heal diabetic foot ulcers

Submission date	Recruitment status
05/07/2013	No longer recruiting
Registration date	**Overall study status**
05/07/2013	Completed
Last Edited	**Condition category**
27/09/2018	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Study website
www.leucopatch.org

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT02224742

Secondary identifying numbers
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

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
15/07/2013

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 ≤108 mmol/mol at screening
5. The cross-sectional area of the index ulcer will be between ≥50 and ≤1000 mm2 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 provided written informed consent
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 269; UK Sample Size: 150

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 (<100x109/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/1.73m2
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 mm2 or larger than 1000 mm2 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 (<100x109/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/1.73m2
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 mm2 or larger than 1000 mm2 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
Denmark

England

Sweden

United Kingdom

Study participating centre

Clinical Trials Unit
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

Sponsor details
Nottingham Health Science Partners
Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Industry

Funder Name
Reapplix (Denmark)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/11/2018		Yes	No
HRA research summary			28/06/2023	No	No