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A multi-centre interventional study to determine patient and clinician impression of different compression therapy options for the treatment of poor leg circulation

Submission date
11/02/2019

Recruitment status
No longer recruiting

Registration date
15/02/2019

Overall study status
Completed

Last Edited
08/06/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Current plain English summary as of 28/02/2020:
Background and study aims
For patients in whom the circulation of the leg is not optimal, the function of the veins in particular may be managed with compression bandaging. Compression bandaging can assist in improving blood flow and reducing swelling of the legs. This study looks at how comfortable two different brands of short-stretch two-layer compression bandaging are for patients. Patients are asked to record the degree of itchiness and other undesirable effects of wearing compression bandaging. The study is also looking to find out the overall impression of comfort, functionality and compliance with each type of compression bandaging as well as any changes to skin characteristics. A clinician's opinion on preference of compression bandage type will also be investigated (for example, by asking them how easy it is to apply each type of bandage). The two different compression bandages used in the study are Coban 2 standard and LITE (manufactured by 3M) and CoFlex TLC Calamine standard and LITE (by Andover Healthcare). Each participant will be its own control and will use identical compression levels for each bandage type.

Who can participate?
Patients aged over 18 who have chronic venous insufficiency (poor blood circulation in the legs) and who would benefit from compression bandaging to control swelling and/or promote healing of any skin damage (including ulcers)

What does the study involve?
Participants complete a number of questionnaires at week 0 (start of study), week 3 and week 6. All questions are in relation to the patient's leg condition and itchiness that may be caused by wearing a compression bandage on the leg. At week 0 they are randomly allocated to one of two treatment groups, either Coban2 Lite or CoFlex TLC calamine Lite compression bandage, and they wear one of the two for the first 3 weeks. Patients switch over to the other bandage at week 3 and wear the second brand of bandage for the second 3 weeks (up to week 6). The only difference is whether they start with Coban2 or CoFlex bandaging. At week 4 and 8, the research

team conduct a follow-up appointment to complete an experience questionnaire and leg and skin characteristics are evaluated. After the 6 week trial period, clinical staff recommence managing the leg – in terms of compression bandage choice - as per routine care.

What are the possible benefits and risks of participating?
Apart from a change in the brand of compression bandage used, the treatment received will not differ from standard treatment and hence the risks are very low. This means that if patients do not take part in the study, then most likely they will be prescribed one of the compression bandage types as part of their normal regular care. Because this study will not significantly affect standard treatment, there is no anticipated immediate benefit expected. However, there is a chance that one of the two bandages that are studied may be more comfortable to wear. At present this is not known and the study is designed to find out if this is the case. As with all compression bandages, there is a risk of damage to the leg if it is not applied properly, and the products used may be irritating to wear for some patients. The study is aimed to investigate how two different compression bandages perform on that front. Participants will not be seen more often by clinical staff , and if clinically indicated the compression bandage may be discontinued or a referral to a specialist may be indicated (again, this is no different from normal clinical practice).

Where is the study run from?
Cumbria Partnership NHS Foundation Trust, North Cumbria University Hospitals NHS, and GP practices in North Cumbria CCG NHS (UK)

When is the study starting and how long is it expected to run for?
December 2018 to November 2019

Who is funding the study?
Andover Healthcare Inc, based in the United States, has provided a non-restricted research grant to fund this project. This means that, although external funding has been received, the results of the study will be reported on and published by the NHS research team without interference from the grant provider. The study team will anonymise the data and it will then be analysed, again by Cumbria Partnership staff. None of the staff at Cumbria Partnership has any conflicts of interest with the company providing the compression bandages.

Who is the main contact?
Dr Stacey Fisher
stacey.fisher@cumbria.nhs.uk

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Who is the main contact?
Dr Stacey Fisher
stacey.fisher@cumbria.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Leon Jonker

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https://orcid.org/0000-0001-5867-4663

Contact details
Science & Innovation Manager
Cumbria Partnership NHS Foundation Trust
E27 Ruskin Corridor
The Carleton Clinic
Cumwhinton Drive
Carlisle
United Kingdom
CA1 3SX
+44 (0)176824 5975
leon.jonker@nihr.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
252438

Central Portfolio Management System (CPMS)
40144

Study information

Scientific Title
A pilot multi-centre, prospective, randomised, controlled crossover trial assessing patient and clinician impression of different two-layer compression therapy options

Acronym
APRICOT

Study objectives
Degree of itchiness experienced by patient with use of the compression bandaging at 4 weeks per treatment regime.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 09/11/2018, Wales REC 6, First Floor, Institute of Life Science 2, Swansea University, Singleton Park, Swansea, SA2 8PP, Tel: +44 (0)1792 606334, Email: penny.beresford@wales.nhs.uk, 09/11/2018, REC ref: 18/WA/0383

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment, Device

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic Venous Insufficiency

Interventions
Current interventions as of 28/02/2020:
Following written consent, at week 0, participants are allocated at random to one of the two arms 1:1 fashion. A randomised sequence from the freeware randomisation programme, see https://www.randomizer.org/ will be used to obtain the randomised list. Sequential envelopes with each next randomisation allocation will be used to achieve concealment and these will be kept in the R&D Department. Research delivery staff will phone the research office to receive information on the next allocation. As the study involves administration of easily recognisable compression bandaging it is not possible to achieve blinding for neither the participants nor the researchers – it is recognised that this increases the risk of bias.

Patients who qualify for compression bandaging treatment will trial a pair of two-layer bandage types, each for 3 weeks. It concerns the current market leader Coban 2 (manufacturer is 3M) and a novel bandage called CoFlex TLC Calamine (Andover Healthcare Inc). Both standard and Lite compression types are permissible. The latter has a primary skin-contact layer that is impregnated with Calamine, a product proven to soothe skin. The study has a randomised crossover design, where patients who are first allocated to Coban2 will then switch over to Coflex TLC Calamine Lite at week 3 to wear the other brand for the second three weeks (to week 6). Full product information on the Coflex TLC Calamine Lite 2-layer compression system can be found on the Andover Healthcare Inc website https://andoverhealthcare.com/product/coflex-tlc-calamine/ . Full product information on the 3M Coban 2-layer compression system can be found on the 3M website: https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Coban-2-Layer-Compression-System?N=5002385+3293321927&rt=rud.

Patients are in the study for a period of 6 weeks. Thereafter, the patient will be followed up as they would be in normal clinical practice. During and after the trial, clinical staff will redress the wound as per routine care, apart from the choice of compression bandaging. The researcher will be in attendance at week 0, 3 and 6 of study participation to randomise the patient and conduct /collect the study participant questionnaires. Unless the patient requests to complete the questionnaire themselves, the researcher will support the participant to complete the questionnaires. Clinicians will complete the questionnaire themselves. The objective is to determine which bandage is best at controlling the undesirable effects of wearing compression bandaging, such as itchiness. Thirty patients and ten treating clinicians will be asked their opinion, and clinical outcome measures will supplement their feedback.

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Patients who qualify for compression bandaging treatment will trial a pair of two-layer bandage types, each for 4 weeks. It concerns the current market leader Coban 2 Lite (manufacturer is 3M) and a novel bandage called CoFlex TLC Calamine Lite (Andover Healthcare Inc). The latter has a primary skin-contact layer that is impregnated with Calamine, a product proven to soothe skin. The study has a randomised crossover design, where patients who are first allocated to Coban2 will then switch over to Coflex TLC Calamine Lite at week 4 to wear the other brand for the second four weeks (to week 8). Full product information on the Coflex TLC Calamine Lite 2-layer compression system can be found on the Andover Healthcare Inc website https://andoverhealthcare.com/product/coflex-tlc-calamine/ . Full product information on the 3M Coban 2-layer compression system can be found on the 3M website: https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Coban-2-Layer-Compression-System?N=5002385+3293321927&rt=rud.

Patients are in the study for a period of 8 weeks. Thereafter, the patient will be followed up as they would be in normal clinical practice. During and after the trial, clinical staff will redress the wound as per routine care, apart from the choice of compression bandaging. The researcher will be in attendance at week 0, 4 and 8 of study participation to randomise the patient and conduct /collect the study participant questionnaires. Unless the patient requests to complete the questionnaire themselves, the researcher will support the participant to complete the questionnaires. Clinicians will complete the questionnaire themselves. The objective is to determine which bandage is best at controlling the undesirable effects of wearing compression bandaging, such as itchiness. Thirty patients and ten treating clinicians will be asked their opinion, and clinical outcome measures will supplement their feedback.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 28/02/2020:
Pruritus levels in the index leg, measured by the severity of pruritus scale (SPS) weeks 0, 3, 6. Week 3 and 6 are used for comparing performance of the two bandages. Week 0 will be available to deduct any baseline presence of itching. Chi-square test will be used for the Severity of Pruritus Scale score. Mann-Whitney U-test will be used for the visual analogue scale for pruritus , and for the 5D itchiness score.

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Previous primary outcome measure:
Pruritus levels in the index leg, measured by the severity of pruritus scale (SPS) weeks 0, 4, 8. Week 4 and 8 are used for comparing performance of the two bandages. Week 0 will be available to deduct any baseline presence of itching. Chi-square test will be used for the Severity

of Pruritus Scale score. Mann-Whitney U-test will be used for the visual analogue scale for pruritus, and for the 5D itchiness score.

Key secondary outcome(s)

Current secondary outcome measures 28/02/2020:
Patient-reported outcome measures:
1. Pruritus scales: SPS, visual analogue scale, 5D (week 0, 3, 6)
2. Venous disease quality of life: CIVIQ20 (week 0, 3, 6)
3. Patient experience upon application of bandage (week 0, week 3)
4. Patient experience of each bandage (week 3, 6)
5. Patient preference (week 6)

Clinical parameters:
1. Skin characteristics and wound status measured with Venous Clinical Severity Score (week 0, 3, 6)
2. Any significant side-effects that required clinical intervention? (week 3, 6)
2.1. Need to either interrupt or discontinue bandage treatment regime?
3. Any generic clinical events? (week 3, 6)
4. Apart from any potential wound dressings, was another product used on the leg? (week 3, 6)
4.1. If so, what product? e.g. Zinc Oxide cream/ointment/paste (including Sudocrem, Desitin)
5. Leg status (week 0, 3, 6):
5.1. Ulcer present: yes/no
5.1.1. If yes,
5.1.1.1. Ulcer location: above calf/calf/below calf
5.1.1.2. Chronicity of ulcer
5.1.1.3. Any evidence on size, if available in medical notes

Clinician bandage preference questionnaire (week 6)

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Previous secondary outcome measures:
Patient-reported outcome measures:
1. Pruritus scales: SPS, visual analogue scale, 5D (week 0, 4, 8)
2. Venous disease quality of life: CIVIQ20 (week 0, 4, 8)
3. Patient experience upon application of bandage (week 0, week 4)
4. Patient experience of each bandage (week 4, 8)
5. Patient preference (week 8)

Clinical parameters:
1. Skin characteristics and wound status measured with Venous Clinical Severity Score (week 0, 4, 8)
2. Any significant side-effects that required clinical intervention? (week 4, 8)
2.1. Need to either interrupt or discontinue bandage treatment regime?
3. Any generic clinical events? (week 4, 8)
4. Apart from any potential wound dressings, was another product used on the leg? (week 4, 8)
4.1. If so, what product? e.g. Zinc Oxide cream/ointment/paste (including Sudocrem, Desitin)
5. Leg status (week 0, 4, 8):
5.1. Ulcer present: yes/no
5.1.1. If yes,
5.1.1.1. Ulcer location: above calf/calf/below calf
5.1.1.2. Chronicity of ulcer
5.1.1.3. Any evidence on size, if available in medical notes

Clinician bandage preference questionnaire (week 8)

Completion date
20/11/2019

Eligibility

Key inclusion criteria
1. Clinical indication to commence, or already started, compression bandaging of the leg. This may due to venous leg ulcer or other qualifying reason. This will be equivalent to a CEAP classification score of C2 or higher (clinical element only – see Appendix 5)
2. ABPI > 0.5, measured within last 12 months. If not yet measured as part of routine clinical care, patients are allowed to be recruited into the trial and ABPI will then be measured. If the measurement is too low, the patient will be withdrawn from the study
3. Adult patients aged > 18 years
4. Mental capacity to give consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
44

Key exclusion criteria
1. Under the age of 18 years
2. Unable to fully understand the consent process and provide informed consent due to either language barriers or mental capacity
3. Limited life expectancy, i.e. undergoing palliative care
4. Active infection in the leg, incl infected venous leg ulcer, cellulitis or otherwise, that requires systematic antibiotic treatment – or within 1 one week of completing antibiotics course. This includes prophylactic antibiotic use
5. Patients who are participating in another research study involving an investigational product that is related to leg, skin, or a co-morbidity that may influence the function of compression bandaging
6. The patient has concurrent (medical) conditions that in the opinion of the investigator may compromise patient safety or study objectives
7. Ankle brachial index < 0.5, measured within 12 months of baseline visit or at baseline of trial

participation
8. Any condition that is contraindicated for the use of any of the compression bandaging used in this trial (including ZnO, Calamine)

Date of first enrolment
13/12/2018

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cumbria Partnership NHS Foundation Trust
Carleton Clinic, R&D department
Cumwhinton Drive
Carlisle
United Kingdom
CA1 3SX

Study participating centre
Carlisle Healthcare
St Paul's Square
Carlisle
United Kingdom
CA1 1DG

Study participating centre
Temple Sowerby Medical Practice
Temple Sowerby
Penrith
United Kingdom
CA10 1RW

Study participating centre

Aspatria Medical Group
Aspatria
United Kingdom
CA7 3HH

Study participating centre
Wigton Group Medical Practice
Wigton
United Kingdom
CA7 9QD

Study participating centre
North Cumbria University Hospitals NHS Trust
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
Cumbria Partnership NHS Foundation Trust

Funder(s)

Funder type
Industry

Funder Name
Andover Healthcare, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/06/2020	08/06/2020	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version v1	05/09/2018	15/02/2019	No	No