

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

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|--|---|---|
| <b>Submission date</b><br>11/02/2019   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>15/02/2019 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>08/06/2020       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> 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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Previous plain English summary:

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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 LITE (manufactured by 3M) and CoFlex TLC Calamine LITE (by Andover Healthcare).

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#### What does the study involve?

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#### 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).

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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

## ORCID ID

<http://orcid.org/0000-0001-5867-4663>

## Contact details

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+44 (0)176824 5975  
[leon.jonker@nihr.ac.uk](mailto:leon.jonker@nihr.ac.uk)

# Additional identifiers

## EudraCT/CTIS number

## IRAS number

252438

## ClinicalTrials.gov number

## Secondary identifying numbers

CPMS 40144, IRAS 252438

# 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

### **Study design**

Randomised; Interventional; Design type: Treatment, Device

### **Primary study design**

Interventional

### **Secondary study design**

Randomised cross over trial

### **Study setting(s)**

Hospital

### **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**

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](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](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 measure

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.

## Secondary outcome measures

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)

#### **Overall study start date**

01/12/2018

#### **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

#### **Age group**

Adult

#### **Lower age limit**

18 Years

#### **Sex**

Both

#### **Target number of participants**

Planned Sample Size: 30; UK Sample Size: 30



**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**

England

United Kingdom

**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**  
**Aspatia Medical Group**  
Aspatia  
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

**Sponsor details**  
Mrs Barbara Cooper  
R&D Manager

The Carleton Clinic  
Cumwhinton Drive  
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England  
United Kingdom  
CA1 3SX  
+44 (0)1228 608926  
barbara.cooper@cumbria.nhs.uk

**Sponsor type**

Hospital/treatment centre

## Funder(s)

**Funder type**

Industry

**Funder Name**

Andover Healthcare, Inc.

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

20/11/2020

**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? |
|--------------------------------------|------------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol file</a>        | version v1 | 05/09/2018   | 15/02/2019 | No             | No              |
| <a href="#">Results article</a>      | results    | 02/06/2020   | 08/06/2020 | Yes            | No              |
| <a href="#">HRA research summary</a> |            |              | 28/06/2023 | No             | No              |