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Intermittent pneumatic compression of the thigh for the treatment of lower limb wounds

Submission date 04/09/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 15/10/2020	**Overall study status** Completed	
Last Edited 20/01/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Most leg ulcers are caused by problems with the veins in the legs and treatment involves wearing firm compression bandages which squeeze the legs and help blood flow to the heart. Unfortunately, some ulcers can be problematic and may persist for months or even years despite being treated with the gold standard treatment of compression bandages. Therefore there is a need to find more ways of helping these problematic ulcers to heal.
Intermittent Pneumatic Compression (or IPC) is another way of compressing legs to try and improve the circulation. The IPCOTT study aims to find out if a new IPC device, known as the WoundExpressTM, can help to heal leg ulcers.

Who can take part?
Most people who have a leg ulcer that is caused by problems with the veins (but not the arteries) will be eligible to take part.

What does the study involve?
Upon entry to the study, participants will be randomly allocated to one of two groups. Group A will be provided with an IPC (WoundExpress) device to use in their home environment for 2 hours daily for the 16-week duration of the study (in addition to continuing to receive their standard wound care). Group B will continue to receive their usual wound care for the 16-week duration of the study. Throughout the 16-week study period, participants will be invited to attend their wound clinic once every two weeks where their leg ulcer and general health will be reassessed.

What are the possible risks and benefits of taking part?
Use of the IPC device may possibly help to reduce the size of leg ulcers and may lessen any ulcer related pain. It is hoped that the information that is gained from this study will help to improve future treatments for patients with leg ulcers.
There are currently no known side effects associated with the use of the IPC (WoundExpress) device.

Where is the study run from?
1. The Welsh Wound Innovation Centre (UK)

2. Accelerate CIC (UK)
3. St. Maria Hilf Krankenhaus, Bochum (Germany)
4. Charité - Universitätsmedizin Berlin (Germany)
5. Karolinska University Hospital, Stockholm (Sweden)

When is the study starting and how long is it expected to run for?
November 2019 to August 2024

Who is funding the study?
1. Huntleigh Healthcare
2. The Accelerate programme which is co-funded by the European Regional Development Fund, through the Welsh Government

Who is the main contact for the study?
Dr Kerry Nyland
Kerry.nyland@arjo.com

Contact information

Type(s)
Public, Scientific

Contact name
Dr Kerry Nyland

Contact details
Huntleigh Healthcare Ltd
35 Portmanmoor Road
Cardiff
United Kingdom
CF24 5HN
+44 (0) 2920 447 038
Kerry.nyland@arjo.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
285979

ClinicalTrials.gov number
NCT05659394

Secondary identifying numbers
IRAS 285979

Study information

Scientific Title
Intermittent Pneumatic Compression of the Thigh for the Treatment of lower limb wounds (IPCOTT): a randomised control trial of IPC plus standard care vs. standard care alone

Acronym
IPCOTT

Study objectives
The addition of thigh-applied, intermittent, pneumatic, compression therapy to standard wound care, for the treatment of venous leg ulcers, will improve ulcer healing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/11/2020, Wales REC 3 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB; +44 (0)2920 230457; Wales.REC3@wales.nhs.uk)

Study design
Multicentre interventional open-label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice, Home

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
Treatment of leg ulceration of venous and mixed aetiology

Interventions
Following a baseline assessment (which will include the collection of information relating to past medical history, current medications, wound history, current wound treatment, and wound measurement and photography), patients will be randomly assigned to treatment groups (group A and group B) using random permuted blocks within each centre. Wound size (≤30cm2, >30cm2) and duration (≤12 months, >12 months) will be stratification factors. An online software application (provided by Sealed Envelope Ltd) will be used for this purpose.

Group A will be the IPC group who will receive a WoundExpress IPC device to be used for two hours daily in the participant's own homes for a 16 week study period. During this time,

participants in group A will also continue to receive their standard wound care. Participants in group B will receive their standard wound care only for the duration of the study. All participants will attend a follow-up appointment every two weeks where wound reassessment including measurement and photography and adherence to the intervention (for participants in group A) will be undertaken.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
WoundExpress a thigh applied intermittent pneumatic compression device

Primary outcome measure
1. Percentage reduction in wound surface area from baseline to week 16 measured using an IPad and InSight® wound imaging software at baseline, 0, 2, 4, 6, 8, 10, 12, 14, and 16 weeks. A wound visual assessment will also be done documenting the condition of the wound bed, wound margin, condition of surrounding skin, and level of exudate. For the purpose of this trial, healing is defined as: 'complete, full, 100% re-epithelialisation or closure without discharge, drainage /scab'.

Secondary outcome measures
1.Patient-reported wound-related pain according to a visual analogue score (VAS) at baseline, 0, 2, 4, 6, 8, 10, 12, 14, and 16 weeks
2. Patient-reported quality of life according to the Cardiff Wound Impact Schedule at baseline, 0, 2, 4, 6, 8, 10, 12, 14, and 16 weeks
3. Proportion of patients with complete wound healing during study 16 week period assessed using an IPad and InSight® wound imaging software at baseline, 0, 2, 4, 6, 8, 10, 12, 14, and 16 weeks

Overall study start date
01/11/2019

Completion date
07/08/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 31/01/2023 (updated 04/09/2023):
1. Age ≥18 years
2. Presence of at least one hard-to-heal*, venous or mixed (of both venous and arterial origin) aetiology lower limb wound
3. ABPI ≥0.6, or, where an ABPI measure is not viable, use of locally-approved alternative assessments to rule out significant peripheral arterial disease i.e. Doppler ausculation, toe pressure assessment (Absolute Toe Pressure ≥40mmHg) or arterial imaging
4. Has received high static compression therapy (in the form of bandages, wraps or hosiery) during the preceding 4 weeks and is willing to continue receiving appropriate static compression

therapy for their ulcer aetiology for the duration of the study
5. Receiving standard wound care as per investigator discretion which will continue regardless of study participation
6. Able and willing to give informed consent for participation in the study
7. Able to self-apply IPC garment (supplied) and connect to an electrically operated pump at home for 2 hours daily for a 16-week period
8. Females of childbearing potential must be willing to use acceptable methods of contraception (birth control pills, barriers or abstinence) during the course of the study and undergo a pregnancy test at screening

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Previous inclusion criteria from 05/03/2021 to 04/09/2023:
1. Age ≥18 years
2. Presence of at least one lower limb wound with venous aetiology, which is hard to heal. For the purpose of this trial, hard to heal is defined as a failure of the wound to progress towards healing (as indicated by a decrease in surface area by ≥25%) in the preceding month, despite appropriate and adequate compression therapy.
3. ABPI ≥ 0.8, or, where an ABPI measure is not viable, use of locally-approved alternative assessments to rule out peripheral arterial disease i.e. Doppler ausculation, toe pressure assessment (TBI > 0.5) or arterial imaging
4. Has received high static compression therapy (in the form of bandages, wraps, or hosiery) during the preceding 4 weeks and is willing to continue receiving high static compression therapy for the duration of the study
5. Able and willing to give informed consent for participation in the study
6. Able to self-apply IPC garment (supplied) and connect to an electrically operated pump at home for two hours daily for a 16-week period

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Previous inclusion criteria:
1. Age ≥18 years
2. Presence of at least one lower limb wound with venous aetiology, which is hard to heal. For the purpose of this trial, hard to heal is defined as a failure of the wound to progress towards healing (as indicated by a decrease in surface area by ≥25%) in preceding month, despite appropriate and adequate compression therapy.
3. Has received high static compression therapy (in the form of bandages, wraps, or hosiery) during the preceding 4 weeks and is willing to continue receiving high static compression therapy for the duration of the study
4. Able and willing to give informed consent for participation in the study
5. Able to self-apply IPC garment (supplied) and connect to an electrically operated pump at home for two hours daily for a 16-week period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Total final enrolment
136

Key exclusion criteria
Current exclusion criteria as of 31/01/2023 (updated 04/09/2023):
1. Wound surface area ≥100cm²
2. Wound duration ≤2 months or ≥ 5 years
3. Diabetic patients with recent HbA1c >8.5
4. Known or suspected deep vein thrombosis (DVT), pulmonary embolism, thrombophlebitis and acute infections of the skin, such as cellulitis
5. Decompensated/severe congestive cardiac failure, pulmonary oedema associated with significant limb oedema or any condition where an increase of fluid to the heart may be detrimental
6. Severe arteriosclerosis or other ischaemic vascular disease
7. Leg ulcers without a venous component to their aetiology (e.g., arterial or rheumatoid) or significant peripheral vascular disease which contraindicates compression (ABI < 0.6 or Absolute Toe Pressure <40 mmHg)
8. Known malignancy
9. Patient receiving any other adjunctive wound therapy such as heat, topical negative therapy, biotherapy
10. Current participation in any other clinical trial
11. Patient likely to miss more than 5 days of therapy (e.g. for planned holiday)
12. Thigh circumference >90 cm (maximum garment size)
13. Any wounds, infection or dermatological conditions that would be adversely affected by placement of the thigh garment
14. Subject is pregnant or breastfeeding

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Previous exclusion criteria from 05/03/2021 to 04/09/2023:
1. Wound surface area ≥100 cm²
2. Wound duration ≤2 months or ≥5 years
3. Diabetic patients with recent HbA1c >8.5
4. Known, or suspected, deep vein thrombosis (DVT), pulmonary embolism, thrombophlebitis, or acute infections of the skin, such as cellulitis
5. Decompensated/severe congestive cardiac failure, pulmonary oedema associated with significant limb oedema, or any condition where an increase of fluid to the heart may be detrimental
6. Severe arteriosclerosis or other ischaemic vascular diseases
7. Leg ulcers of non-venous aetiology (e.g., arterial or rheumatoid) or significant peripheral vascular disease which contraindicates full compression (ABPI < 0.8 or TBI ≤ 0.5)
8. Known malignancy
9. Receiving any other adjunctive wound therapy such as heat, topical negative therapy, biotherapy
10. Current participation in any other clinical trial

11. Likely to miss more than five days of therapy (e.g. for planned holiday)
12. Thigh circumference >73 cm (maximum garment size)

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Previous exclusion criteria:
1. Wound surface area ≥100 cm²
2. Wound duration ≤2 months or ≥5 years
3. Diabetic patients with recent HbA1c >8.5
4. Known, or suspected, deep vein thrombosis (DVT), pulmonary embolism, thrombophlebitis, or acute infections of the skin, such as cellulitis
5. Decompensated/severe congestive cardiac failure, pulmonary oedema associated with significant limb oedema, or any condition where an increase of fluid to the heart may be detrimental
6. Severe arteriosclerosis or other ischaemic vascular diseases
7. ABPI ≤0.8 or ≥1.3
8. Known malignancy
9. Receiving any other adjunctive wound therapy such as heat, topical negative therapy, biotherapy
10. Current participation in any other clinical trial
11. Likely to miss more than five days of therapy (e.g. for planned holiday)
12. Thigh circumference >73 cm (maximum garment size)

Date of first enrolment
08/03/2021

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
England

Germany

Sweden

United Kingdom

United States of America

Wales

Study participating centre
Welsh Wound Innovation Centre
Rhodfa Marics
Ynysmaerdy
Pontyclun

Rhondda Cynon Taf
Pontyclun
United Kingdom
CF72 8UX

Study participating centre
Accelerate CIC
Centenary Wing
St Joseph's Hospice
Mare St
Hackney
London
United Kingdom
E8 4SA

Study participating centre
St. Maria Hilf Krankenhaus
Hiltroper Landwehr 11-13
Bochum
United Kingdom
44805

Study participating centre
Charité - Universitätsmedizin Berlin
Department of Geriatric medicine
Geriatrics Research Group
Nursing Research Group
Reinickendorfer Str. 61
Berlin
Germany
13347

Study participating centre
Karolinska University Hospital
7. Karolinska University Hospital
Stockholm
Sweden
SE-171 76

Study participating centre

Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Mid Yorkshire Hospitals NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
SerenaGroup Monroeville
4318 Northern Pike suite 201
Monroeville
United States of America
15146

Study participating centre
Three Rivers Wound and Hyperbaric Center
2565 Toledo Blade Blvd
North Port
United States of America
34289

Study participating centre
Wound Care of Tulsa
PC 4538 South Harvard Ave
Tulsa
United States of America
74135

Study participating centre
Royal Research
3911 Hollywood Blvd Suite 10

Hollywood
United Kingdom
33021

Study participating centre
Titan Research
2601 N. 3rd Suite 201A
Phoenix
United States of America
85004

Sponsor information

Organisation
Huntleigh Healthcare Ltd

Sponsor details
35 Portmanmoor Road
Cardiff
Wales
United Kingdom
CF24 5HN
+44 (0)2920 485885
kerry.nyland@arjo.com

Sponsor type
Industry

Website
https://www.huntleigh-diagnostics.com/

Funder(s)

Funder type
Industry

Funder Name
Huntleigh Healthcare Ltd

Funder Name

Welsh Government and European Regional Development Fund

Results and Publications

Publication and dissemination plan
Results will be published in a high impact peer reviewed journal.

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date