Lower Limb Iscchaemia FlowOx Treatment

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Also called LLIFT

Pilot study to test the clinical efficacy of FlowOx home treatment compared to the standard care patients with critical limb ischemia and lower limb ulcers get.

Why try FlowOx? Here is the rationale:

- Peripheral artery disease (PAD) – increases morbidity, decreases mobility and decreases the quality of life.
- Critical limb ischemia (CLI) could cause tissue loss, infection, and lower limb amputation.
- Pharmacologic agents bring modest improvements in rest pain.
- Drug therapy, control of risk factors, and revascularisation procedures can help CLI, some patients get worse - more tissue viability loss.
- Revascularisation procedures often fail or even make things worse.
- Intermittent negative pressure (INP) therapy has been explored.

The technology we're talking about in this lecture involves intermittent pneumatic compression therapy.

It's a boot called FlowOx technology

The limb is suspended within the boot

It's not in contact with the boot itself

Patients must sit while undergoing the treatment

FlowOx is manufactured by Otivio

http://www.otivio.com/flowox

Intermittent negative pressure has been selected because it's low pressure - because continuous pressure increases blood flow, but it's NOT maintained. Therefore, intermittent was selected. Patient must wear the device 30 minutes – 2 hours.

After 8 weeks of treatment, there is:

- A significant improvement in wound healing
- Reduction in size of the wound
- Improvement in color

You can get a cushion made specifically to fit the contours of your body. You'd think that would be the best envelopment available and it IS – for the first week. Often, bodies change, especially after spinal cord injuries. (slide #19, #20 and #21) Initially, after a spinal cord accident, the body will lose some weight. But shortly, because the body isn't moving/active, it will GAIN. If a person with a customized cushion gains weight, the cushion is DOING MORE DAMAGE than good.

> **Primary outcome:**
>
> a change in the size of the ulcer after three months.

Secondary outcomes: (1-3 months)

- Clinical improvement of the ulcer
- Quality of sleep
- Lower amputation incidence
- Cost effectiveness

Trial design:

- SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Guidelines
- A multicentre, pragmatic, open, two-arm, assessor blind, randomised controlled trial
- Block stratified randomisation (FlowOx: standard care, 2:1)
- Sample size: 15 (10:5)
- Setting: 3 NHS clinical sites (Vascular Clinics).

Monitor adherence of how much people are using the device because the device records when it's used

Also doing health economics analysis – is this worthwhile?

Also conducing patient focus group to study usability (what do patients think about this device?) as well as clinicians (what do they think of the device?)

Ask the patient to take the device home and ask them to use it for up to 2 hours every single day for 3 months. The device records all the treatment times.

Control treatment consists of ulcer dressing and pain management.

Inclusion criteria:

- Adults capable of giving informed consent
- CLI: absent foot pulses and monophasic or absent Doppler signals PLUS 2 of: ischaemic rest pain, ankle systolic is less than 50mmHg, deteriorating wound
- Lower limb ulcer: grade 0 - 2 that has not healed in six weeks
- Interventional procedures like revascularization either failed, patient not eligible, or declined
- Show size smaller than 46 and circumference of ankle 36 cm or less

Exclusion criteria:

- Pressure or venous ulcers, cellulitis, or acute limb ischaemia
- Vasospastic; collagen vascular disease; vasculitis; atheroembolic disease and arterial trauma
- History of recent DVT or multiple cases in the past
- Within 6 months of surgery, past or future, or lower extremity revascularisation
- Engaged in cardiac rehabilitation

- Inflammatory skin condition such as eczema or psoriasis
- Cancer
- Pregnancy
- Unable to use device independently
- Already involved in a study on lower limb ischaemia

The exclusion criteria is to get robust data, and also to ensure patient safety – the exclusion criteria requires that they can apply the device to their lower limb

Patients were screened in vascular clinics for eligibility

Provided info about the trial

Have 48 hours to consider taking part

Then enter the clinics for baseline measures and randomization into relevant treatment group

Then, trained how to use the device

FlowOx group contacted by at 24 hours and 7 days to make sure they're happy with the device and have no problems

Photos and data collected after 1, 2, and 3 months from both FlowOx group and standard clinical treatment group.

Also, there is on-call staff in case of emergency if the limb starts to deteriorate

Study not yet completed, therefore no published results as of yet.