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Outcomes of cold and compression therapy following anterior cruciate ligament reconstruction.

Submission date
26/09/2024

Recruitment status
No longer recruiting

Registration date
17/10/2024

Overall study status
Completed

Last Edited
22/11/2024

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cryotherapy following knee surgery is an established method for improving outcomes such as pain and patient satisfaction in the acute postoperative period. The addition of compression to cryotherapy is believed to further accentuate these improvements. Cryocompression therapy has historically been applied through the use of ice packs and bandages, but advances in technology have resulted in the development of electronic devices that provide user-modifiable compression and a continuous flow of temperature-controlled water through a cuff wrapped around the treatment area. A recent systematic review of the literature concluded that such technologically advanced cryocompression devices may enhance the positive effects afforded by the application of cold and pressure following surgical procedures. The Physiolab S1 is one such cryocompression device that is yet to be clinically evaluated in a formal study. One of its benefits is its portability meaning it can be transported and easily operated within clinical or domestic settings. This is particularly relevant for patients undergoing day-case surgical procedures such as anterior cruciate ligament reconstruction, as portable devices mean that patients can receive the same cryocompression treatments at home as they would otherwise during a hospital stay. This study compares outcomes following day-case anterior cruciate ligament reconstruction in patients who use a Physiolab S1 cryocompression device versus those who use traditional icing methods.

Who can participate?
Patients aged 18 years old and over who are scheduled to undergo anterior cruciate ligament reconstruction with one of the three participating surgeons on one leg with no additional ligament procedures being conducted at the same time.

What does the study involve?
Following surgery, patients in the Treatment Group will first have the cuff of the Physiolab S1 device wrapped around their knee by a trained member of the team, and a 30-minute treatment will be conducted following the manufacturer’s recommendations: the device will circulate water through the cuff at a constant 8 while applying intermittent compression of 25-50 mmHg. Patients in the Control Group will have an ice pack applied to their knee by a trained member of

the team for 30 minutes. Subsequent treatments will be applied in the same way every four hours while the patient is in hospital. After being discharged from the hospital on the first postoperative day, patients will be instructed to apply a final cryotherapy treatment before going to bed that evening. Then participants will be instructed to apply cryotherapy to their operated knee as soon as they wake up in the morning, and every four waking hours throughout the day, for the first 14 post-operative days.

What are the possible benefits and risks of participating?
No additional benefit or risk is expected for participants in the Control Group as they will receive everything as per the current standard of care at the host hospital. Participants in the Treatment Group are predicted to receive an equal or greater improvement in measured outcomes compared to the Control Group as a result of their use of the Physiolab S1 device. Participation in this study is considered to be low risk for causing additional complications beyond those associated with standard surgical procedures and cryotherapy treatments since the exclusion criteria are designed to ensure that no patients at high risk of adverse reactions to the cryotherapy provided by the Physiolab S1 are recruited.

Where is the study run from?
The Knee Research Team is based at Basingstoke and North Hampshire Hospital, Basingstoke, Hampshire, England.

When is the study starting and how long is it expected to run for?
Recruitment is expected to begin in November 2024, and the final data are expected to be collected by August 2025.

Who is funding the study?
Physiolab Technologies Ltd are providing funding and equipment for the study.

Who is the main contact?
Mr Aadil Mumith (Chief Investigator, Consultant Orthopaedic Surgeon), aadil.mumith@hhft.nhs.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
332948

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2023 SPON-AM-311023

Study information

Scientific Title
Comparison of outcomes when using an ice pack or electronic cryocompression device following ACL reconstruction: a randomised controlled trial

Acronym
CryoACLr

Study objectives
Pre- to post-operative improvements in outcomes will be observed for both groups. There will be significant differences in outcomes between groups in favour of the group that uses the electronic cryocompression device.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending submission NHS Research Ethics Committee

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improvement of clinical outcomes following ACL reconstructive surgery

Interventions
This study is a single-centre randomized controlled trial involving two groups with one receiving cryocompression treatments using a Physiolab S1 cryocompression device and the other group using ice packs and bandages as per the current standard-of-care in the host institution.

Experimental group: Physiolab S1 cryocompression device treatment every 4 waking hours following surgery for the first 14 postoperative days. The device will apply 8 and 25-50 mmHg for 30 minutes at a time.

Control group: Standard of care (ice packs and bandages) applied every 4 waking hours following surgery for the first 14 postoperative days. Treatments will each last for 30 minutes.

Randomisation will be performed in advance of participant recruitment using a random number generator, where “1” represents the experimental group and “2” represents the control group.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Physiolab S1

Primary outcome(s)
Subjective pain measured using a numerical pain rating scale at baseline and post-op days 0, 1, 7 and 14

Key secondary outcome(s))
1. Satisfaction with the surgery measured using a 5-point Likert scale to respond to the question "Overall, how would you rate the early result of your ACL reconstruction?" with options ranging from "Terrible" to "Excellent" at postoperative days 0, 1, 7 and 14
2. Satisfaction with the cryotherapy measured using a 5-point Likert scale to respond to the question "Overall, how satisfied are you with the cryotherapy treatments you have received today?" with options ranging from "Very unsatisfied" to "Very satisfied" at postoperative days 0, 1, 7 and 14
3. Ease-of-use of Physiolab S1 device (experimental group only) measured using a 5-point Likert scale to respond to the question "Overall, how easy have you found the Physiolab S1 device to use?" with options ranging from "Very difficult" to "Very easy" at postoperative days 0, 1, 7 and 14
4. Complications measured using hospital records following each participant's 14th

postoperative day
5. Protocol adherence measured using a self-reported log of cryotherapy treatment frequency, time, method, and settings (where relevant) recorded daily for the first 14 postoperative days.
6. Use-of-analgesia measured using a self-reported log of any analgesic medication taken (time, type, dosage) recorded daily for the first 14 postoperative days

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Adult patients of the 3 participating surgeons
2. Scheduled for unilateral ACL reconstruction surgery

Patients with any of the below relative contraindications for cryotherapy may be included in the study but will be closely monitored during and immediately following cryotherapy treatments. Any adverse events that are identified will result in the immediate cessation of treatment and removal of that patient from the study. Relative contraindications include:
1. Diabetes
2. A loss of sensation in the intended therapy area
3. Confirmed or suspected tissue infection in the treatment area
4. History of frostbite on the affected limb or therapy area
5. An unstable fracture in the treatment area
6. An unstable localised skin condition in the intended therapy area
7. Heart failure
8. Raynaud’s phenomenon or cold hypersensitivity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
150 years

Sex
All

Key exclusion criteria
1. Undergoing additional ligament procedure(s) simultaneously
2. Cold urticaria/allergy
3. Known haematological condition that affects clotting

4. Regenerating nerves under the intended therapy area
5. Tissues affected by tuberculosis in the intended therapy area
6. Current or suspected deep vein thrombosis and/or pulmonary embolus
7. Nervous system damage causing muscle tightness with a reduced ability to stretch
8. Cognitive impairment/disabilities or communication barriers
9. Significantly impaired circulation in the intended therapy area
10. Chronic wounds near the intended therapy area
11. Malignant tumour in the affected limb or therapy area
12. Haemorrhaging tissue or any untreated haemorrhagic disorders

Date of first enrolment
01/02/2025

Date of final enrolment
01/07/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hampshire Hospitals NHS Foundation Trust
Basingstoke and North Hampshire Hos
Aldermaston Road
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RG24 9NA

Sponsor information

Organisation
Hampshire Hospitals NHS Foundation Trust

ROR
https://ror.org/04shzs249

Funder(s)

Funder type
Industry

Funder Name
Physiolab Technologies Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Mr Aadil Mumith (aadil.mumith@hhft.nhs.uk). The raw collected data will be available in an anonymised format upon request, preventing any of the participants from being identified. Such data that will be available includes recorded outcomes, sex, age, and allocated study group. Identifiable information such as name, date of birth, date of surgery (etc) will not be made available. It will be removed from any such dataset that might be shared publicly following the completion of the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes