ISRCTN51736090 https://doi.org/10.1186/ISRCTN51736090

A comparison of skin temperature changes around the knee when using cryo-compression devices

Submission date
11/10/2023

Recruitment status
No longer recruiting

Registration date
18/10/2023

Overall study status
Completed

Last Edited
10/09/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Cryotherapy after surgery is widely utilised and has numerous practical applications for post-operative rehabilitation. Previous research has suggested that during cold therapy, the skin temperature of the knee should be reduced to 10-15°C to maximise the therapeutic benefits of cooling while avoiding the risk of cold injuries such as nerve damage and frostbite. However, a recent study noted that where cryocompression devices have previously been used to reduce the skin temperature to <10°C, no complications relating to the device have been reported, suggesting that the risk to the user at these lower temperatures is minimal. The temperature range at which a cryocompression device should be set in order to achieve a skin temperature within the therapeutic range of 10-15°C is unknown. Modern cryotherapy devices often consist of some sort of cuff that can be wrapped around the knee, with a connecting tube to a central unit that supplies and circulates ice water to and from the cuff in order to cool the intended body part. Such devices offer differing levels of control over the temperature of the ice water as it leaves the central unit, but nothing is known about how this correlates to the skin temperatures that are achieved during a cryotherapy treatment. The aim of this study is to determine the ability of five different cryocompression devices to effectively lower the skin temperature of the treatment area to within the therapeutic range.

Who can participate?
Any adult aged over 18 years old who does not currently have any knee pain/injury

What does the study involve?
Five 1-hour trips to the Physiology Laboratory at the University of Winchester (UK). The first trip will involve signing a consent form and having some basic measures taken (height, age, mass, BMI) before undergoing a 30-minute cryocompression treatment with one of the five devices being tested in the study. Treatment consists of sitting on a therapy bed with a cuff wrapped around the knee, which connects to a device that applies mild pressure and circulates cold water through the cuff to cool your knee. A thermometer will be taped to your knee before the cuff is

applied and skin temperature readings will be recorded before, and every 5 minutes during, the cryocompression treatment. The subsequent 4 sessions in the laboratory will consist of single 30-minute treatments using each of the remaining devices being tested.

What are the possible benefits and risks of participating?
By participating in this study, you will be helping to improve an area of clinical research that aims to optimise recovery and outcomes for patients around the world who undergo surgery in the future. There is a slightly increased risk of cold injury if your skin temperature is reduced to below 10°C for an extended period of time (>60 mins). Since none of the tests will last longer than this length of time, it is not expected that there is any significant risk of cold injury. It is possible that the application of the cryotherapy device will make you feel generally cold while you are wearing the cuff. You are free to wear warm clothing on your upper body and we will have blankets on hand to make you feel more comfortable, should you begin to feel too cold during your participation. If you experience severe discomfort or any other adverse reaction during testing, you are free to terminate the test and withdraw from the study, should you wish to do so.

We will be using some personal information in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study either during participation or within 7 days of completing your participation, we will destroy any data of yours that we have collected. After 7 days of your completed participation, your data will be anonymised and untraceable back to you. To safeguard your rights, we will use the minimum personally identifiable information possible. This research study complies with Article 6(1)(e) of the GDPR regulations with data being processed under the basis of public task and in accordance with 5.23 of the University's Articles of Association. For further information please contact the lead investigator with regards to obtaining the University of Winchester's Data Protection Policy.

Where is the study run from?
The Physiology Laboratory at the University of Winchester (UK)

When is the study starting and how long is it expected to run for?
January 2022 to December 2022

Who is funding the study?
Physiolab Technologies Ltd (UK)

Who is the main contact?
James Belsey, KneeResearch@pm.me (UK)

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr James Belsey

ORCID ID

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT05355116

Secondary identifying numbers
Nil known

Study information

Scientific Title
A comparison of skin temperature changes around the knee of 32 participants using five different cryocompression devices: a randomised crossover trial

Acronym
CryoSkinTempRCT

Study objectives
All devices will significantly reduce skin temperature compared to pre-treatment levels. Not all devices will successfully reduce skin temperature to within 10-15°C

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/03/2022, University of Winchester, Faculty of Health & Wellbeing Ethics Committee (Sparkford Road, Winchester, SO22 4NR, United Kingdom; +44 (0)1962 675226; HWB_Ethics@winchester.ac.uk), ref: HWB_REC_ 220228_Faulkner_Belsey

Study design
Single-centre interventional randomized crossover trial

Primary study design

Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Laboratory

Study type(s)
Treatment, Efficacy

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
Basic science study with health population investigating the change in skin temperature when undergoing a cryocompression treatment around the knee. Cryocompression therapy intended to improve post-operative outcomes for a variety of knee surgeries.

Interventions
Five different cryocompression devices will comprise the five study conditions in the randomised crossover trial. A random number generator will be used to determine the order in which each participant receives a cryocompression treatment with each device, and to which leg the treatments will always be applied.

The study involves 5 1-hour trips to the Physiology Laboratory at the University of Winchester (UK). The first trip will involve signing a consent form and having some basic measures taken (height, age, mass, BMI) before undergoing a 30-minute cryocompression treatment with one of the five devices being tested in the study. A treatment consists of sitting on a therapy bed with a cuff wrapped around the knee, which connects to a device that applies mild pressure and circulates cold water through the cuff to cool your knee. A thermometer will be taped to your knee before the cuff is applied and skin temperature readings will be recorded before, and every 5 minutes during, the cryocompression treatment. The subsequent 4 sessions in the laboratory will consist of single 30-minute treatments using each of the remaining devices being tested.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Physiolab S1, GameReady, Breg VPulse, Aircast Cryo/Cuff, Koolcare Gel Wrap

Primary outcome measure
Skin temperature measured using a thermometer before and every 5 minutes during the cryocompression treatment

Secondary outcome measures
1. Time taken to achieve a skin temperature within 10-15°C, time spent within this temperature range and the mean difference between device temperature setting and measured skin temperature measured using a thermometer before and every 5 minutes during the cryocompression treatment
2. Subjective rating of comfort measured using a 5-point Likert scale (very comfortable; comfortable; neutral; uncomfortable; very uncomfortable) to respond to the question "How comfortable did you find the treatment you just experienced?" immediately following the recording of the final skin temperature measurement at the end of a test

Overall study start date
06/01/2022

Completion date
05/12/2022

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. No current knee pain or injury

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
30

Total final enrolment
32

Key exclusion criteria
1. BMI >40 kg/m2
2. History of nerve damage or sensory deficit in the lower limbs (inc. frostbite)
3. Hypersensitivity to cold (inc. hives)
4. Active inflammation or pain of the knee
5. History of thrombosis, embolism, or other conditions related to impaired peripheral circulation

6. Suffering from diagnosed diabetes, multiple sclerosis, rheumatoid arthritis, spinal cord injury, cardiovascular disease, hypertension, Raynaud's phenomenon, cryoglobulinemia, or hemoglobinuria
7. Confirmed or suspected tissue infection, an unstable fracture, a skin condition, or tumour in the treatment area
8. Cognitive impairment or communication barriers

Date of first enrolment
15/03/2022

Date of final enrolment
05/12/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Winchester
Sparkford Road
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Sponsor information

Organisation
University of Winchester

Sponsor details
Department of Sport, Health & Community
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+44 (0)1962841515
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Sponsor type
University/education

Website

https://winchester.ac.uk/

ROR
https://ror.org/03fmjzx88

Funder(s)

Funder type
Industry

Funder Name
Physiolab Technologies Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact and peer-reviewed journal

Intention to publish date
05/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr James Belsey, kneeresearch@pm.me.

The type of data to be shared includes age, sex, leg, height, weight, BMI, skin temperature, and comfort rating. As the study has been completed, the anonymised dataset can be provided within 3 working days of receipt of a request. Information pertaining to the sharing of anonymised data was included as part of the process. All participant names have been removed from the dataset along with participant ID numbers and the specific dates of each testing session undertaken. There are no ethical or legal restrictions to report.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/01/2024	10/09/2024	Yes	No