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Clinical outcomes after total knee replacement using two cryocompression devices after surgery

Submission date
28/11/2024

Recruitment status
Recruiting

Registration date
16/01/2025

Overall study status
Ongoing

Last Edited
11/06/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The application of cold and pressure following knee surgery is known to result in superior clinical outcomes compared to when none is used. Cryocompression therapy aims to reduce swelling, inflammation, and pain by reducing blood flow and nerve sensitivity in the area. There are several different technologies available that provide cryocompression therapy with varying levels of control over treatment variables. Gravity-assisted devices and electronic continuous cold-flow devices both work by taking ice water from a central reservoir to a cuff wrapped around the desired therapy area. The cuff of gravity-assisted devices is filled with cold water and then left in situ until it re-warms, at which point the cuff can be drained and re-filled with more cold water. Electronic devices continuously pump user-determined temperature-controlled water through the cuff from the central reservoir, while the cuff applies a pre-selected level of compression. This study aims to compare the clinical outcomes of patients following total knee replacement surgery when using either a gravity-assisted or electronic cryocompression device as part of their acute post-operative rehabilitation. This will allow clinicians and patients in future to choose the most effective modality for cryocompression therapy to improve and optimise post-operative outcomes.

Who can participate?
Adult patients undergoing unilateral primary total knee replacement surgery at Spire Methley Park Hospital in the UK

What does the study involve?
Participants will be randomised to receive either a gravity-assisted or electronic device to be used in the hospital following their operation and for the first 2 postoperative weeks while at home. Treatments will be applied for 30 minutes, every 2 waking hours for the first 2 postoperative weeks by either clinical staff (while in hospital) or the patient themselves (while at home). Participants will complete subjective outcome scores daily for the first 14 days after surgery.

What are the possible benefits and risks of participating?
There are no additional benefits or risks to patients receiving the gravity-assisted device, as this represents the current standard of care within the hospital. There is a potential additional benefit to participants in the experimental group as the electronic device is expected to result in greater improvements in clinical outcomes. There is no foreseen additional risk for users of the electronic device as it will be used within its UKCA-marked purpose. As long as participants adhere to the prescribed treatment frequency outlined above, the risk of adverse events as a result of the cryocompression treatments is deemed to be extremely low. Participants will be trained while in the hospital by a clinical member of staff to show them how to apply each device correctly and to discuss the appropriate treatment protocol, along with the potential risks of deviating from it.

Where is the study run from?
Spire Methley Park Hospital (Leeds, UK)

When is the study starting and how long is it expected to run for?
June 2024 to May 2026. Recruitment is expected to start in August 2025 and run until the end of April 2026.

Who is funding the study?
There is no monetary funding for the study, though Physiolab Technologies Ltd is acting as the sponsor for the study and will provide the electronic devices that will be used by the experimental group.

Who is the main contact?
Catherine Venable, Physiotherapy Manager, catherine.venable@spirehealthcare.com

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
345621

Protocol serial number
1.0

Study information

Scientific Title
Outcomes after total knee arthroplasty when using either a gravity-assisted or electronic continuous cold-flow cryocompression device during the acute postoperative period

Acronym
CryoTKA

Study objectives
Pre- to post-operative improvements in clinical outcomes will be observed within both groups. The degree of improvement will be greater in the group using the electronic device compared to the gravity-assisted device.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/06/2025, East of England - Cambridge East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048181; cambridgeeast.rec@hra.nhs.uk), ref: 25/EE/0078

Primary study design
Interventional

Study design
Single-centre multi-surgeon randomized controlled trial

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Clinical outcomes for patients following unilateral total knee arthroplasty

Interventions
Patients will be randomised to receive cryocompression therapy using either an electronic continuous cold-flow device (experimental group) or a gravity-assisted cryocompression device (control group - current standard-of-care within the hospital). 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, and patients will be allocated to a group in order of the randomised sequence at the point of recruitment. Treatments will be applied in 30-minute bouts every 2 waking hours after surgery, for the first 14 post-operative days. The electronic device will be set to apply a continuous temperature of 8 and intermittent compression of 25-50mmHG throughout each treatment. The gravity-assisted device does not allow for the selection of applied temperatures and pressures.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Physiolab S1 continuous cold-flow device. ProMedics CryoPro device.

Primary outcome(s)
Subjective pain using a Numerical Pain Rating Scale measured at baseline, then on post-operative days 1, 7, and 14.

Key secondary outcome(s)
1. Range-of-motion measured using a goniometer at baseline, then on postoperative days 1 and 7
2. Swelling measured using a tape measure at baseline, then on postoperative days 1 and 7
3. Patient satisfaction with the surgery measured using a 5-point Likert scale to answer the question "Overall, how would you rate the early result of your knee replacement?” on postoperative days 1, 7, and 14
4. Patient satisfaction with the cryotherapy measured using a 5-point Likert scale to answer the question “Overall, how satisfied are you with the cryotherapy treatments you have received today?” on postoperative days 1, 7, and 14
5. Ease-of-use of cryotherapy device measured using a 5-point Likert scale to answer the question “overall, how easy have you found your cryotherapy device to use?” on postoperative days 1, 7, and 14
6. Use of analgesia (including time, type, and dose) measured using data logged daily on hospital records (while in hospital) and within a data-collection pack by the patient (while at home)
7. Knee function measured using an Oxford Knee Score at baseline and on postoperative day 14

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Adults scheduled to undergo TKA at Spire Methley Park Hospital (Leeds, UK)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
150 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Revision TKA
2. Bilateral TKA
3. Cold urticaria/allergy
4. Known haematological condition that affects clotting
5. Regenerating nerves under the intended therapy area
6. Tissues affected by tuberculosis in the intended therapy area
7. Current or suspected deep vein thrombosis and/or pulmonary embolus
8. Nervous system damage causing muscle tightness with a reduced ability to stretch
9. Cognitive impairment/disabilities or communication barriers
10. Significantly impaired circulation in the intended therapy area
11. Chronic wounds near the intended therapy area
12. Malignant tumour in the affected limb or therapy area
13. Haemorrhaging tissue or any untreated haemorrhagic disorders

Date of first enrolment
20/08/2025

Date of final enrolment
30/11/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Spire Methley Park Hospital
Methley Lane
Methley
Leeds
England
LS26 9HG

Sponsor information

Organisation
Physiolab Technologies Ltd

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 Dr James Belsey (KneeResearch@pm.me)

IPD sharing plan summary
Available on request