

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

Submission date 28/11/2024	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/01/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/01/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 December 2025. Recruitment is expected to start in January 2025 and run until the end of July 2025.

Who is funding the study?

There is no monetary funding for the study, though Physioblab 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)

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

345621

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Old ethics approval format

Ethics approval(s)

Pending submission: NHS Research Ethics Committee

Study design

Single-centre multi-surgeon randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home, Hospital, Medical and other records

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

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Physiolab S1 continuous cold-flow device. ProMedics CryoPro device.

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

06/06/2024

Completion date

31/12/2025

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Age group

Mixed

Lower age limit

18 Years

Upper age limit

150 Years

Sex

Both

Target number of participants

52

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

01/01/2025

Date of final enrolment

31/07/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Spire Methley Park Hospital**

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Sponsor type

Industry

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Funder(s)

Funder type

Industry

Funder Name

Physiolab Technologies Ltd

Results and Publications

Publication and dissemination plan

Planned presentation of results at (inter)national scientific conferences, and publication in a peer-reviewed journal.

Intention to publish date

01/09/2025

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