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NICE ICE Trial: A comparison of an iceless cooling compression device with traditional ice pack therapy

Submission date
19/06/2025

Recruitment status
Not yet recruiting

Registration date
20/06/2025

Overall study status
Ongoing

Last Edited
20/06/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
After knee replacement surgery, many people experience pain and swelling. Traditionally, ice packs are used to help with this. A new device has been developed that cools and gently compresses the knee without using ice. This study is comparing the new device to standard ice packs to see which works better at reducing pain, swelling, and helping people recover more comfortably after surgery.

Who can participate?
Adults aged 18 or older who are having their first knee replacement at the National Orthopaedic Hospital Cappagh may be eligible. People with certain medical conditions, a very high body mass index (BMI over 40), or who are unable to follow the treatment plan will not be able to take part.

What does the study involve?
Participants will be randomly placed into one of two groups: one group will use regular ice packs, and the other will use the new cooling and compression device. Both treatments will be applied six times a day for 20 minutes during the hospital stay. The research team will monitor pain levels, knee movement, swelling, and medication use. Participants will also be asked how satisfied they were with their treatment.

What are the possible benefits and risks of participating?
Participants may benefit from improved comfort and recovery after surgery. The study may also help improve care for future patients. Risks are low, but some people may find the cooling uncomfortable or experience minor skin irritation. All treatments used are considered safe and are already used in clinical practice.

Where is the study run from?
The study is being carried out at the National Orthopaedic Hospital Cappagh in Dublin (Ireland)

When is the study starting and how long is it expected to run for?
January 2025 to December 2025.

Who is funding the study?
The study is funded by Consultant Innovation Funding from the Health Service Executive (Ireland)

Who is the main contact?
Mr James Cashman, Consultant Orthopaedic Surgeon at the National Orthopaedic Hospital Cappagh, james.cashman@gmail.com

Contact information

Type(s)
Principal Investigator

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Mr James Cashman

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Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NOHC-2025-ETH-MB-CEO-378

Study information

Scientific Title
NICE ICE Trial: A randomised control trial investigating the effect of iceless compression cryotherapy with traditional ice pack therapy on post-operative outcomes in patients undergoing total knee arthroplasty

Acronym
NICE ICE TRIAL

Study objectives
The aim of this study is to investigate does a device which combines pneumatic compression with cryotherapy offer an advantage over traditional ice packs

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/02/2025, The National Orthopaedic Hospital Cappagh, Finglas, Dublin 11 Registered Charity Number (RCN): 20058685 (Cappagh Hospital, Finglas, Dublin, D11EV29, Ireland; +353 1814000; mary.byrne@nohc.ie), ref: NOHC-2025-ETH-MB-CEO-378

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Post-operative patients following Total Knee Arthroplasty

Interventions
A. Ice pack therapy for 20 minutes 6 times per day
B. NICE1 Cold compression device for 20 minutes 6 times per day

Treatment will only be for the duration of post-operative admission. Follow up will be at routine post-op review but all outcomes will be recorded at time of discharge. Randomisation will be

performed with a sealed envelope. Each participant will have a sealed envelope with their assigned treatment record and this will be opened in recovery and treatment commenced. These will be distributed randomly into the patients chart on admission.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
NICE ICE Compression Machine

Primary outcome measure
1. Pain intensity is measured using the Visual Analogue Scale (VAS) at 6, 12, 24, and 48 hours post-operatively
2. Opioid consumption is measured using medication administration records during the inpatient stay

Secondary outcome measures
1. Knee range of motion (flexion and extension) is measured using a goniometer at baseline, 6, 12, 24, and 48 hours post-operatively
2.Limb swelling is measured using mid-patella circumference at baseline, 6, 12, 24, and 48 hours post-operatively
3. Patient satisfaction is measured using a patient satisfaction questionnaire at discharge
4. Adverse events and tolerability issues are measured using clinical observation and patient self-reporting during the inpatient stay and at discharge
5. Length of stay measured using patient records
6. Time to physio discharge measured using patient records

Overall study start date
14/01/2025

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Undergoing primary TKA at NOHC
3. Able to provide informed consent
4. End stage arthritis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. BMI >40 kg/m²
2. Cognitive impairment
3. Prior infection or vascular compromise in the operative limb
4. Refusal or inability to comply with assigned treatment
5. Use of another post-operative cooling therapy outside of the study protocol

Date of first enrolment
01/08/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Ireland

Study participating centre
National Orthopaedic Hospital Cappagh
Cappagh Road, Finglas
Dublin
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D11EV29

Sponsor information

Organisation
Cappagh National Orthopaedic Hospital

Sponsor details
National Orthopaedic Hospital Cappagh, Finglas
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Sponsor type
Hospital/treatment centre

Website
http://www.nohc.ie/

ROR
https://ror.org/03vc5bf16

Funder(s)

Funder type
Government

Funder Name
Irish Consultant Public only contract SPARK Funding

Results and Publications

Publication and dissemination plan
Study findings will be shared through peer-reviewed publication and presentations. Participants may request a lay summary upon study completion.

Intention to publish date
01/03/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be stored on a non-publicly available repository.

Type of Data Stored: The participant-level data includes pseudonymised data on demographics (e.g., age, gender, BMI), clinical information (pain scores, analgesic use, time to physiotherapy discharge), therapy adherence, and satisfaction scores. Identifiable data (such as names and hospital numbers) are removed or replaced with study IDs.

Repository Name: Currently, the data is stored securely on the internal servers of the National Orthopaedic Hospital Cappagh (NOHC). While not a public data repository, the infrastructure complies with GDPR and local data protection standards.

Persistent Weblink: This is not applicable. Data is not yet hosted on an external repository with a persistent DOI or weblink.

Process for Requesting Access: Researchers seeking access to the dataset should contact the Principal Investigator (Mr. James Cashman) or designated co-investigator (Joshua Hayes) via NOHC. Requests will be evaluated based on scientific merit, ethical approval, and data protection compliance.

Timing for Availability: Data will become available following publication of the primary results, anticipated by the end of 2025. Requests may be considered earlier on a case-by-case basis, subject to REC approval.

Consent from Participants: Yes, explicit informed consent will be obtained from all participants, as documented in the signed consent form. This included consent for data usage in the study and optional consent for future related research with additional approval.

Data Anonymisation: Data is pseudonymised upon collection. The re-identification key is securely held by the designated team member (Ciara Doran) on a password-protected hospital computer. Only authorised study personnel have access. For any external sharing, data will be fully anonymised.

Ethical or Legal Restrictions: All data processing is conducted under the legal basis of public interest in the area of healthcare as per Article 9(2)(i) of the GDPR and in accordance with the Irish Health Research Regulations. Ethical approval has been granted by the National Orthopaedic Hospital Research Ethics Committee.

Additional Comments: Data will be retained securely for five years post-study completion, then deleted. All data handling adheres to NOHC's Data Protection Policy, and study personnel have completed required HSE Land data protection training. Results will be published in peer-reviewed literature and may be presented at conferences.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			20/06/2025	No	Yes
Protocol file			20/06/2025	No	No