NATIONAL ORTHOPAEDIC HOSPITAL CAPPAGH		
National Orthopaedic Hospital Cappagh, Finglas, Dublin 11.	**Research Study Protocol**	

Study Title

NICE ICE Trial: A Randomised Controlled Trial Comparing an Ice Pack Versus an Iceless Cooling Compression Device in Total Knee Arthroplasty

Principal Investigator

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Sponsor

National Orthopaedic Hospital Cappagh

Funding Source

Consultant Innovation Funding.
This research is non-commercial in nature.

Background and Rationale

Post-operative pain and swelling are common following total knee arthroplasty (TKA). Standard management includes the application of ice packs to reduce inflammation and discomfort. A newer modality, an iceless cooling compression device, has been developed to deliver consistent cooling and compression without the use of ice. This study aims to compare the effectiveness of this device against standard ice pack therapy in managing pain, swelling, and recovery during the inpatient stay following TKA.

Objectives

Primary Objective:
To compare the effects of an iceless cooling compression device versus standard ice packs on post-operative pain following TKA.

Secondary Objectives:
- To compare the effects on knee range of motion (ROM) and swelling.
- To evaluate patient satisfaction.
- To monitor opioid usage in both groups.
- To assess safety and tolerability of the cooling methods.

Study Design

A single-centre, prospective, randomised controlled trial with two parallel arms and 1:1 allocation.

Sample Size

A total of 120 patients undergoing primary total knee arthroplasty will be enrolled (60 per group). This sample size is deemed adequate to detect clinically meaningful differences in pain and recovery outcomes during the acute post-operative period.

Study Setting

National Orthopaedic Hospital Cappagh, Dublin

Eligibility Criteria

Inclusion Criteria:
- Age ≥18 years
- Undergoing primary TKA at NOHC
- Able to provide informed consent
- End stage arthritis

Exclusion Criteria:
- BMI >40
- Cognitive impairment
- Prior infection or vascular compromise in the operative limb
- Refusal or inability to comply with assigned treatment
- Use of another post-operative cooling therapy outside of the study protocol

Recruitment and Consent Process

Patients scheduled for TKA will be approached during their preoperative consultation or hospital admission. They will receive an information leaflet and a consent form. Informed consent will be obtained before enrolment. Participation is entirely voluntary.

Randomisation

Participants will be randomly assigned (1:1) to one of two groups using a sealed envelope method. Allocation will be concealed until post-operative assignment. 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 Groups

Group A – Standard Ice Pack Therapy:
- Application of c ice packs without compression
- 20-minute sessions, 6 times daily, spaced by a minimum 1-hour break

Group B – Iceless Cooling Compression Device:
- Application of a cooling and compression device set at 5°C, with adjustable pneumatic compression
- 20-minute sessions, 6 times daily, with minimum 1-hour breaks
- Pressure settings: low pressure (days 0–2), medium pressure (days 3–5)

Both interventions will be administered by staff during the inpatient stay and self-managed thereafter if discharge occurs within the 5-day window.

Study Procedures and Assessments

Timepoint	Assessments
Pre-op (baseline)	Demographics, medical history, baseline VAS, ROM, knee circumference
6, 12, 24, 48 hours post-op	VAS (pain), ROM (flexion/extension), mid-patella circumference
During hospital stay	Analgesia use, physiotherapy progress
Discharge	Patient satisfaction questionnaire, adverse events

Outcome Measures

Primary Outcome:
- Pain scores using Visual Analogue Scale (VAS) at specified post-op intervals

Secondary Outcomes:
- Knee range of motion (flexion/extension)
- Limb swelling (mid-patella circumference)
- Analgesic (opioid) consumption
- Patient satisfaction
- Adverse events or tolerability issues

Data Management and Confidentiality

All data will be anonymised and stored on secure hospital systems. Personal data will be handled according to GDPR regulations and Irish Health Research Regulations. Data will be retained for 5 years post-study.

Statistical Analysis

Descriptive statistics will summarise baseline data. Between-group comparisons will use t-tests or non-parametric equivalents. Repeated measures will be analysed using linear mixed models. Significance will be set at $p < 0.05$. All analysis will follow an intention-to-treat principle.

Ethical Considerations

This study has received ethical approval from the National Orthopaedic Hospital Research Ethics Committee. Participation is voluntary and withdrawal may occur at any time. All participants will be informed of potential risks and benefits.

Safety Monitoring

All adverse events will be recorded and reviewed by the study team. Serious events will be reported to the ethics committee in accordance with standard procedures.

Dissemination

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