Study Participant Information Leaflet

STUDY NAME	NICE ICE Trial: A randomized control trial comparing an Ice Pack versus an Iceless Cooling Compression Device in Total Knee Arthroplasty
Identification Number for study:	

Principal Investigator(s) and Co-Investigator(s)	Joshua Hayes, Specialist Registrar, joshuahayes@rcsi.ie Ciara Doran, Physician Associate, ciara.doran@nohc.ie James Cashman, Consultant Surgeon, (ciara.doran@nohc.ie)
Data Controllers	**National Orthopaedic Hospital Cappagh**
Data Protection Officer	**Data Protection Officer: Claire Falvey** **Contact details: dpo@nohc.ie and (01) 814 2447.**

- You are invited to take part in a research study that is being done by Mr James Cashman at the National Orthopaedic Hospital Cappagh.
- Before you decide whether or not you wish to take part, please read this information sheet carefully. Ask Mr Cashman or his team any questions. Don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. You may wish to discuss it with your family, friends or GP.
- This leaflet has five main parts:
    - Part 1 – The Research Project
    - Part 2 – Data Protection
    - Part 3 – Costs, Funding and Approval
    - Part 4 – Future Research
    - Part 5 – Further Information

Part 1 – The Research Project

Why is this study being done?

After knee replacement surgery, patients often use ice packs to help with pain and swelling. We want to see if a new cooling device might work better. Your participation will help us understand which method is more effective.

Why have I been invited to take part?

- You are being invited to take part in a research study at the National Orthopaedic Hospital in Cappagh. This study is looking at how well a new cooling device works compared to the standard ice pack therapy that patients usually get after knee replacement surgery. We intend to recruit 120 patients to participate in the study.

Do I have to take part? Can I withdraw?

- Participation in this study is completely on a voluntary basis. Your knee replacement surgery will not be impacted by your decision to participate or not in this study.
- If you choose not to participate in this study there will be no adverse consequences affecting you or your treatment.
- Yes, you can change your mind at any time, even after you've agreed to take part. If you decide to leave the study, your decision will not affect your care or treatment. You don't need to give a reason, and you can withdraw by simply telling your doctor or the research team. You will not be required to give a reason for wanting to withdraw from the study.
- If you wish to withdraw from the study you can contact Joshua Hayes through the hospital phoneline 01-8140400.

What happens if I change my mind?

If you decide to leave the study at any time, that's completely okay. You don't need to give a reason, and it won't affect your care or treatment. You can simply tell your doctor or a member of the nursing team, and they will stop collecting data from you. Any information collected up to that point may still be used in the study unless you ask for it to be removed.

How will the study be carried out?

When will the study take place?

The study will take place during your hospital stay after your knee replacement surgery. Data will be collected before your surgery and at specific times after your surgery (e.g., 6, 12, 24, and 48 hours post-surgery).

Where will the study take place?

The study will take place at the National Orthopaedic Hospital in Cappagh, where you will be recovering after your surgery.

What will happen in general terms?

- Before your surgery, we will collect some basic information about you.
- After your surgery, you will either use the standard ice packs or a new cooling device as part of your recovery.
- We will check your pain, swelling, and recovery progress at specific times after your surgery.
- Your physiotherapy progress will be recorded until you leave the hospital.
- We will also keep track of any pain medications you take.

How many patients will be taking part in the study?

Around 120 patients will take part in this study. Your participation will help us compare the new cooling device to the standard ice pack therapy and improve care for future patients.

What will happen to me if I decide to take part?

If you decide to take part in this study, here's what will happen step by step:

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1. Before Your Surgery

- **Where:** At the National Orthopaedic Hospital in Cappagh.
- **What happens:**
  - During your pre-surgery consultation or hospital admission, we will explain the study to you and ask if you'd like to take part.
  - If you agree, we will collect some basic information about your health, medical history, and current condition.
  - You will be asked to sign this consent form to confirm your participation.

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2. After Your Surgery

- **Where:** In your hospital room at the National Orthopaedic Hospital.
- **What happens:**
  - After your knee replacement surgery, you will be randomly assigned to one of two groups:
    - **Group 1:** You will receive the **standard ice pack therapy** (the usual care for pain and swelling after surgery).
    - **Group 2:** You will use a **new cooling device** (an experimental method to help with pain and swelling).
  - Random assignment means it's like flipping a coin to decide which group you'll be in. This helps us compare the two methods fairly.
  - Both methods are designed to help with pain and swelling, and you will receive the same high standard of care regardless of which group you're in.

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3. During Your Hospital Stay

- **Where:** In your hospital room and during physiotherapy sessions.
- **What happens:**
  - We will check your pain, swelling, and recovery progress at specific times after your surgery (e.g., 6, 12, 24, and 48 hours post-surgery).

- Your physiotherapist will record your progress during your usual physiotherapy sessions.
- We will also keep track of any pain medications you take during your recovery.
- Your participation in the study will not change your usual care or recovery plan.

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4. What is expected of you:

- You will need to follow the therapy plan given to you (either ice packs or the new cooling device).
- You will be asked to let us know if you have any problems or concerns during your recovery.

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5. How long will you be involved?

- Your involvement in the study will last only during your hospital stay.
- Once you are discharged from the hospital, your participation in the study will end.

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6. What parts are research and what parts are standard care?

- **Standard care:** Your knee replacement surgery, physiotherapy, ice pack and pain management are part of your usual care and will not change.
- **Research:** The use of the new cooling device (if you are assigned to that group) and the additional checks on your pain, swelling, and recovery are part of the study.

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7. What if the new cooling device doesn't work for me?

- If you experience any issues with the new cooling device, you can let the research team know immediately, and they will adjust your care as needed.

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8. Will there be any extra visits or tests?

- No, all study activities will take place during your normal hospital stay. There will be no extra visits or tests required.

What will happen to my Samples and Data?

Your privacy is very important to us. Here's how we will handle your data:

1. **How will my data be collected?**
    - We will collect information about your health, recovery, and pain levels before and after your surgery. This includes details from your medical records, physiotherapy sessions, and pain medication use.
2. **How will my data be stored?**
    - All your data will be stored securely and kept confidential. It will only be accessible to the research team and will be protected by hospital privacy policies.
3. **How will my data be used?**
    - Your data will be used to compare the effectiveness of the new cooling device to the standard ice pack therapy.
    - The results of the study may be published in medical journals or presented at conferences, but your name and personal details will never be shared.
4. **Who will have access to my data?**
    - Only the research team and authorised hospital staff will have access to your data.
    - Your data will not be shared with anyone outside the study without your permission.
5. **How long will my data be kept?**
    - Your data will be kept for 5 years after the study ends. After that, it will be securely destroyed.
6. **Can I withdraw my data?**
    - Yes, if you decide to leave the study, you can also ask for your data to be removed. However, once the study results are published, it may not be possible to remove your data from the analysis.

Are there any benefits to taking part in this research?

While there may not be direct benefits to you, taking part in this study could help in the following ways:

1. **Potential benefits to you:**
    - If you are assigned to use the **new cooling device**, you may experience better pain relief or faster recovery compared to the standard ice packs.
    - You will receive close monitoring and care from the research team during your recovery.
2. **Benefits to others:**
    - Your participation will help us learn more about the best ways to manage pain and swelling after knee replacement surgery.
    - This could improve care for future patients who have the same surgery.
3. **Contributing to medical knowledge:**
    - By taking part, you are helping to advance medical research and improve treatments for people with knee arthritis.

Are there any risks to me or others if I take part?

Taking part in this study is generally safe, but there are a few things to be aware of:

1. **Risks to you:**
    - If you are assigned to use the **new cooling device**, there is a small chance it might not work as well as the standard ice packs or could cause minor discomfort (e.g., skin irritation or feeling too cold).
    - If you experience any problems, you can tell the research team right away, and they will adjust your care as needed.
    - Your participation in the study will not affect the quality of your medical care or recovery.
2. **Risks to others:**
    - There are no risks to others (e.g., family, friends, or hospital staff) from your participation in this study.
3. **What if something goes wrong?**
    - The research team will monitor you closely during the study. If any issues arise, they will address them immediately.

- If you experience any unexpected problems related to the study, you will still receive the same high standard of care from the hospital.

4. **Confidentiality:**
   - We will do everything we can to protect your privacy and keep your information confidential. However, there is a very small risk of a breach of confidentiality (e.g., if data is accidentally shared). If this happens, we will take steps to fix the issue as quickly as possible.
5. **Seeking a second opinion:**
   - You are entitled to seek a second opinion about your treatment or participation in this study at any time. This will not affect your care or your relationship with the hospital.

What happens if something goes wrong when I'm taking part in the study?

Your safety is our top priority. If something goes wrong while you're taking part in the study, here's what will happen:

1. **Immediate help:**
   - If you experience any problems or discomfort, tell the research team or your doctor right away. They will take steps to address the issue and make sure you're safe.
2. **Medical care:**
   - You will continue to receive the same high standard of care from the hospital, even if the problem is related to the study.
3. **Insurance:**
   - If something goes wrong because of the study, the hospital has insurance to cover your care.
4. **Reporting the issue:**
   - Any problems related to the study will be reported to the hospital's ethics committee and the relevant authorities to ensure the study is as safe as possible for everyone.

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

- You will not receive individual results from the study, but you can ask for a summary of the overall findings once the study is complete.
- If any tests or investigations during the study reveal something that could affect your health, you will be informed immediately.
- The results of the research will be shared in medical journals or conferences, but your personal details will not be included.

Part 2 – Data Protection

What information about me (personal data) will be used as part of this study? Will my medical records be accessed?

1. **What information will be used?**
    - We will collect information about your health, such as your medical history, details about your knee replacement surgery, and your recovery progress (e.g., pain levels, swelling, and physiotherapy results).
    - We will also record any pain medications you take during your recovery.
2. **Will my medical records be accessed?**
    - Yes, the research team will access your medical records to collect the information needed for the study. This will only include information relevant to the research.
3. **How will my information be protected?**
    - Your personal data will be kept confidential and stored securely. Only the research team and authorised hospital staff will have access to it.
    - Your name and personal details will not be shared in any reports or publications

What will happen to my personal data?

- Your personal data (e.g., medical history, surgery details, and recovery progress) will be used only for this study and kept secure.
- Only the research team and authorised staff will access your data. It will not be shared with third parties without your permission.
- Your data will be stored for 5 years after the study ends and then securely destroyed.
- Your data will not leave the State and will not be used for automated decision-making or profiling.
- Your privacy is protected, and your data will not be used in a way that causes harm or distress.

Who will access and use my personal data as part of this study?

- Your personal data will be accessed by the **research team**, including the Principal Investigator (PI), Co-Investigators, and authorised staff at the National Orthopaedic Hospital in Cappagh.
- Your medical records may also be reviewed by the research team to collect relevant information.
- Your data will not be shared with third parties outside the study team unless required by law or with your permission.
- Your data will **not leave the hospital, Ireland, or the EU** and will be stored securely at all times.

Will my personal data be kept confidential? How will my data be kept safe?

- Your privacy is important to us. We will keep your personal data confidential and secure.
- Your data will be stored in password-protected systems and only accessed by the research team, who are bound by strict confidentiality rules.
- A **Data Protection Impact Assessment** has been completed to ensure your data is handled safely and in line with data protection laws.
- Your data will not be shared in a way that identifies you in any presentations or publications.
- The research team has received training in data protection to ensure your information is handled responsibly.
- If something goes wrong, we will take immediate steps to fix the issue and inform you if necessary.

What is the lawful basis to use my personal data?

- By law, we can use your personal data for scientific research in the public interest under **Article 6(1)(e)** and **Article 9(2)(j)** of the GDPR.
- We will also ask for your **explicit consent** to use your data, as required by the Irish Health Research Regulations.

What are my rights?

You have the following rights regarding your personal data:

- **Access:** You can request a copy of your data.
- **Restrict or object:** You can restrict or object to how your data is used.
- **Correct or delete:** You can ask for inaccurate data to be corrected or deleted.
- **Data portability:** You can request your data in a portable format to transfer to another organisation.
- **Delete:** You can ask for your data to be deleted, unless it would make the research impossible or very difficult.

To exercise these rights, contact your study doctor Joshua Hayes or the NOHC Data Protection Officer.

Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

Provide details of the **research ethics committee** that gave ethical approval to the research including:

- The **name and contact details** of the committee that gave ethical approval to the research (does not need to be a named individual);
- Whether any of the persons carrying out the research have **a link** to the committee or the institution behind the committee;
- The **date** ethical approval was given by the committee;
- **Reporting arrangements** agreed with the committee;
- Any **conditions** attached to the research by the committee.

SAMPLE TEXT:

Yes, this study has been approved by the National Orthopaedic Hospital Research Ethics Committee. Approval was granted on [INSERT DATE].

Who is organising and funding this study? Will the results be used for commercial purposes?

- This study is being conducted by the research team at the National Orthopaedic Hospital in Cappagh.
- It is funded by **Consultant Innovation Funding**.
- The research is not being conducted for commercial purposes, and the results will not be used for profit.
- No one is being paid to recruit patients for this study.

Is there any payment for taking part? Will it cost me anything if I agree to take part?

- No, we are not paying patients to take part in the study. However, you will be reimbursed for travel expenses if you need to make any visits that you would not normally have made as part of your routine clinical care.

Part 4 – Future Research

Will my personal data and/or biological material be used in future studies? (May not apply)

Will my personal data and/or biological material be used in future studies?

- We are asking for your permission to store your personal data and/or biological material for possible use in **future research studies**.
- These future studies would be in the same general area of health research (e.g., knee replacement recovery) and would require ethics approval.
- Your data/material could be used by our research team or other researchers, but only if they meet the same strict data protection and ethical standards.
- Your participation in future research is **voluntary**. You can withdraw your consent for future use at any time by contacting Mr James Cashman.

Part 5 – Further Information

Who should I contact for information or complaints?

If you have any questions or concerns, you can contact:

- **Principal Investigator:** Mr James Cashman, National Orthopaedic Hospital Cappagh, 01-8140400
- **Data Protection Officer:** Claire Falvey, dpo@nohc.ie.

If you are not satisfied with how your data is handled, you can lodge a complaint with the **Office of the Data Protection Commission**, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

Will I be contacted again?

- You will not be contacted after this study unless there are **clinically relevant results** that you need to know about.
- If you agree to future research, we may contact you about other studies, but you can opt out at any time.

If you agree to take part, you will be asked to sign the Consent Form on the next page. You will receive a copy of this leaflet and your signed form to keep.