ISRCTN17454353 https://doi.org/10.1186/ISRCTN17454353

Evaluation of different knee cooling devices to control pain after knee replacement surgery

Submission date
14/07/2023

Recruitment status
Recruiting

Registration date
08/05/2024

Overall study status
Ongoing

Last Edited
04/04/2025

Condition category
Musculoskeletal Diseases

[_] 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
Medial osteoarthritis – wearing of the inside of the knee joint – can be treated with knee replacement procedures, where either part or the whole of the knee joint is replaced. For all major knee operations, post-surgery the site of operation can be painful. Increased pain may limit a patient's progress with post-operative mobilisation. Therefore, research is already ongoing in the field of knee surgery to determine if different type of bandaging and cooling of the affected leg post-surgery may improve patient and clinical outcomes. A relatively new method is now available which involves a combination of active compression and cooling, rather than passive compression and cooling. This may reduce pain. This present study aims to assess if active compression and cooling is better than standard passive compression and cooling in terms of keeping a patient comfortable by reducing pain and possibly improving other clinical outcomes too.

Who can participate?
Patients aged 18 years or older, listed for knee arthroplasty (replacement) surgery, who in the opinion of the treating surgeon, that compression & cooling therapy may be of benefit.

What does the study involve?
This study involves a comparative evaluation of two different types of cooling therapy that is applied to the knee joint of patient who have just undergone a knee replacement operation. Straight after surgery, patients will receive either a standard cooling sleeve (cryo/cuff) or a cooling brace that also compresses (VPULSE); the latter is designed to both cool the joint and stimulate blood flow with the intermittent compression action. Pain levels are measured at various intervals and compared for the two different cooling device interventions. Other parts of the knee surgery and recovery management of patients is left unchanged.

What are the possible benefits and risks of participating?
It may be the case that one type of cooling therapy, either standard or with added intermittent compression, gives a patient more pain relief than the other. No additional risks are anticipated for patients. Both devices are approved for this intended use and measures are in place to avoid too much cooling or too much compression.

Where is the study run from?
North Cumbria Integrated Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2023 to September 2026

Who is funding the study?
Joint Operations Ltd (UK)

Who is the main contact?
Dr Leon Jonker, Leon.jonker@ncic.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Leon Jonker

ORCID ID
https://orcid.org/0000-0001-5867-4663

Contact details
R&D Department
North Cumbria Integrated Care NHS Foundation Trust
Penrith
United Kingdom
CA11 8HX
+44 1768 245975
Leon.jonker@ncic.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
322564

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55347, IRAS 322564

Study information

Scientific Title

ALASKA trial, A single-centre, two-arm, controlled, prospective randomized trial comparing AIRCAST® KNEE CRYO/CUFF™ passive compressive cryotherapy with VPULSE® active compressive cryotherapy after knee arthroplasty surgery

Acronym
ALASKA trial

Study objectives
The main objective of the study is whether VPULSE® is significantly better than standard AIRCAST® KNEE CRYO/CUFF™ for pain control post-surgery when measured on a visual display pain scale.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/03/2023, London - City & East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 207 104 8124; cityandeast.rec@hra.nhs.uk), ref: 23/LO/0186

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 additional files

Health condition(s) or problem(s) studied
Post surgical pain management in knee replacement for osteoarthritis

Interventions
Control (standard care) arm - AIRCAST® KNEE CRYO/CUFF™
Once the operation is finished, a wound dressing is applied and a standard bandage is applied. It consists of one layer of soft synthetic bandage, stretching from proximal tibia to distal femur covered by a further layer of crepe bandage prior to or after tourniquet deflation, with 50% overlap of each layer. Once transferred to the ward for recovery, this standard bandage will be removed and AIRCAST® KNEE CRYO/CUFF™ cryotherapy is applied to the patient's index knee. This is a sleeve containing iced water and it will be utilised for up to 48 hours post-operation or until patient discharge, whichever of the two is sooner.
The CRYO/CUFF™ is designed to combine the therapeutic benefits of controlled cold

compression to minimise hemarthrosis and swelling and reduce pain. The cuff is anatomically designed to completely fit the knee providing maximum coverage of the whole joint and allowing the whole surface area to have the continual cooling benefit of cryotherapy. The cuff is attached to the Gravity Aircast Cryo/Cuff Cooler and will hold water and ice needed for six to eight hours of cryotherapy.

Intervention arm - VPULSE®
Once the operation is finished, a wound dressing is applied and a standard bandage is applied. It consists of one layer of soft synthetic bandage, stretching from proximal tibia to distal femur covered by a further layer of crepe bandage prior to or after tourniquet deflation, with 50% overlap of each layer. Once transferred to the ward for recovery, this standard bandage will be removed and VPULSE compression cryotherapy is applied to the patient's index knee.
As with standard treatment arm, the VPULSE cuff is applied over the routine surgical wound dressing. The cryotherapy effect is achieved by circulating cold water using a pump rather than gravity-driven cryotherapy with the current Aircast Cryo/Cuff set up that is standard care. The VPULSE also achieves compression by intermittent dynamic compression; this is an approximate pressure of 50mmHG. Further info regarding VPULSE can be obtained from the Joint Operations website: https://www.jointoperations.co.uk/buy-online/vpulse/

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
AIRCAST® KNEE CRYO/CUFF™, VPULSE®

Primary outcome measure
1. Pain at rest is measured using the visual display scale (VDS) at baseline at pre-surgery, and 1, 3, 5,12 days and 6 weeks post-surgery
2. Pain (walking) is measured using the visual display scale (VDS) at baseline at pre-surgery, and 1, 3, 5,12 days and 6 weeks post-surgery
3. Types of pain are measured using the McGill pain questionnaire at baseline at pre-surgery, and 1, 3, 5,12 days and 6 weeks post-surgery
4. Knee limb range of motion is measured with a goniometer at baseline at pre-surgery, and 6 weeks post-surgery
5. Knee functionality is measured with validated KOOS score at baseline at pre-surgery, and 6, 12 weeks post-surgery
6. Patient satisfaction with the allocated cooling therapy is measured at 5 days post-surgery

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
08/03/2023

Completion date

30/09/2026

Eligibility

Key inclusion criteria
1. Patient who is listed for knee arthroplasty (replacement) surgery, either partial or total knee replacement (unilateral).
2. Clinical indication, in the opinion of the treating surgeon, that compression & cooling therapy may be of benefit to the patient
3. Adult patients aged > 18 years
4. Mental capacity to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 88; UK Sample Size: 88

Key exclusion criteria
1. Under the age of 18 years
2. Unable to fully understand the consent process and provide informed consent due to either language barriers or mental capacity
3. Revision of previous knee replacement or osteotomy on the index leg.
4. Limited life expectancy, i.e. undergoing palliative care
5. Any condition that is associated with excessive bleeding, coagulation abnormalities or any other significant haematological condition (e.g. Factor V Leiden, haemophilia).
6. Cardiovascular or vascular condition that in the opinion of the treating surgeon contraindicates the use of compression bandaging, including moderate to severe peripheral arterial disease, venous leg ulcer, high dose anti-coagulant medication
7. Any skin or other condition that contraindicates the use of compression and cooling therapy.
8. Patients who are participating in another interventional research study involving an investigational product related to the knee procedure and its aftercare.
9. The patient has concurrent (medical) conditions that in the opinion of the investigator may compromise patient safety or study objectives.
10. Patient has practical or mobility issues which will prevent them from removing the device themselves

Date of first enrolment
01/04/2023

Date of final enrolment

31/05/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
North Cumbria Integrated Care NHS Foundation Trust

Sponsor details
Pillars Building
Cumberland Infirmary
Infirmary Street
Carlisle
England
United Kingdom
CA2 7HY
+44 1228608926
dave.dagnan@ncic.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.ncic.nhs.uk/

ROR
https://ror.org/003hq9m95

Funder(s)

Funder type

Industry

Funder Name
Joint Operations Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	23/06/2023	14/07/2023	No	Yes
Protocol file	version 2.0	23/06/2023	14/07/2023	No	No
Protocol file	version 2.1	29/11/2024	04/04/2025	No	No