Effect of cryo- and compression therapy after Total Knee and Unicompartmental Arthroplasty, A Randomised Controlled Trial*

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Primary objective:Investigating the effect of the use of cryo- and compression therapy during the first 6 postoperative weeks after surgery (TKA en UKA) on the perceived pain in rest at 6 weeks postoperative.Secundary objectives:Investigating the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON53761

Source
ToetsingOnline

Brief title
Cryo en compression therapy after TKA and UKA

Condition

- Bone and joint therapeutic procedures

Synonym
total knee replacement and partial knee replacement

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis

Source(s) of monetary or material Support: een subsidie is toegekend door de Wetenschappelijke Adviesraad (WAR) van de LROI (landelijke registratie orthopedische interventies). ,U sport, in het kader van het onderzoek wordt er een gereduceerd tarief voor de brace gehanteerd

Intervention

Keyword: cryotherapy, patient reported outcome measures (PROMs), Total Knee Arthroplasty, Unicompartmental Arthroplasty

Outcome measures

Primary outcome

The primary endpoint is the 11-point NRS pain scale will be used to rate the perceived pain at rest (where 0 indicates no pain and 10 indicates extreme pain) 6 weeks postoperatively.

Secondary outcome

The 11-point NRS pain scale in rest will also be assessed preoperatively, daily during the first 6 postoperative weeks and at 6 and 12 months postoperatively as a secondary outcome.

The 11-point NRS pain scale will also be used to rate the perceived pain during loading as a secondary study parameter. This scale will be assessed preoperatively, at 6 weeks, and at 6 and 12 months postoperatively. The NRS pain scale will be daily scored for the first 6 weeks.

Other secondary study parameters are the Knee injury and Osteoarthritis Outcome Score (KOOS) and the Work, Osteoarthritis and joint-Replacement Questionnaire (WORQ) questionnaire. KOOS contains five different subscales and is considered valid and reliable to evaluate knee problems experienced by patients in different contexts. The Sport and Recreation Function subscale was not used as

it was considered to be irrelevant to this study, given that patients were not likely to practice sports during the first six postoperative weeks. The score for each subscale ranges from 0 to 100, where 0 indicates the worst possible knee problems. The WORQ is a reliable, valid and responsive instrument to score the impact of knee complaints on work following TKA. The score ranges between 0 and 100, where 0 indicates inability to perform work-related knee-loading activities. Both questionnaires are assessed preoperative and 6 weeks postoperative.

The other questionnaires that are administered as secondary outcomes are part of the standard PROMs set (part of usual care). These questionnaires are: the EQ5D-5L as a measure of the general health status (index score and VAS scale 0-100), the Oxford knee score that measures pain and function of the knee (score range 0-48) and the KOOS-PS as a short measure of physical functioning of the knee (score range 0-100). These questionnaires are administered preoperative, after 6 weeks (extra for this trial), 6 months and 12 months. At the postoperative measurement moments (6 weeks (extra for this trial), 6 months and 12 months) in addition several anchor questions are assessed, these questions concern patient perceived changes regarding pain and daily functioning (7 point Likert scale), as well as patient satisfaction (NRS scale 0-10).

Furthermore, the opiod use will be assessed as a secondary outcome measure. All participants will be asked to document their use of escape pain medication daily during the six postoperative weeks when in excessive pain.

Physical examination tests consist of the active range of motion measurement, knee circumference measurement and Timed Up and Go (TUG) test. Active range of motion (AROM) will be measured with a goniometer using maximal active flexion and extension. AROM is a reliable measurement for knee joint motion. The circumference is measured to assess swelling of the knee. It will be determined in a relaxed extended knee at three locations: mid-patella, 7 cm proximally and 7 cm distally of the patella. The knee circumference measurement is shown to be reliable. The TUG is a commonly used and reliable performance-based test that measures functional mobility. Patients will be instructed to stand up from a chair, walk at a comfortable speed to a 3-metres mark, turn around, walk back to the chair, and sit down. Time is measured in seconds from the start sign until sit-down. Patients will be allowed to use their crutches or walker, as needed. The same chair will be used for all measurements. All three measurements will be done preoperatively and at 6 weeks postoperatively.

The compliance with the intervention therapy will also be obtained as a secundary outcome measure, which will be determined based on the log where patients document the number of times they have used the cryo-and compression brace during the 6 postoperative weeks.

Study description

Background summary

Total and unicompartmental knee arthroplasty (TKA/UKA) are widely accepted and effective treatment options for end-stage osteoarthritis (OA) of the knee.

Significant long-term improvement in pain, function and quality of life after TKA are reported in literature, yet rehabilitation in the first three months remains challenging.Pain and swelling due to inflammatory reaction after tissue damage may obstruct effective rehabilitation in the early postoperative period. This could result in stiffness of the knee and patient dissatisfaction, also in the long-term. Differences in the rehabilitation have been found between UKA and TKA patients, where UKA patients have less postoperative complications, a better and faster recovery after surgery, and less pain and opioid use that may be explained by the less invasive nature of the UKA surgery. Despite encouraging results after implementing rapid recovery protocols with perioperative local infiltration analgesia and early mobilisation, treatment after both treatments could still be optimised. In general, opioid use is common in the early postoperative period after a TKA and - to a lesser extend - an UKA. Negative side effects (e.g., nausea, vomiting, dizziness) and the increasing abuse of opioid analgesics in modern society drives the search for alternative analgesic techniques. Cryotherapy could play a role in optimising rehabilitation after surgery. Cryotherapy involves the application of cold to the skin surrounding injured soft tissue. Application of cold reduces local blood flow due to vasoconstriction and ensuing the local inflammatory reaction, swelling and heat experience.

The effectiveness of cryotherapy on the recovery after surgery was studied in numerous studies in mainly TKA patients and in the majority - but not in all - of these studies a beneficial effect of the cold therapy was found. Adie et al (2010) show in a systematic review and meta-analysis based on 11 RCT*s that using cryotherapy the blood loss is significant lower and the range of motion is higher at discharge. In addition, a small effect on pain is found, cryotherapy leads to lower levels of pain at day 2. This effect was not found at day 1 and 3. No differences were found in complications, analgesics use, length of stay and swelling. Functioning was only measured in one study, so no conclusions could be drawn about that variable. These authors concluded that using cryotherapy postoperatively after a TKA might have benefits, but that the clinical relevance was uncertain. A more recent review performed by Ni et al (2015) confirmed, based on 12 studies, the beneficial results concerning blood loss and pain reduction on day 2. Also, no complications were documented related to the cryotherapy.

Sadoghi et al. (2018) focused on the effects of cryotherapy starting in the first postoperative week and found significant beneficial effects on pain on day 2 and knee flexion on day 6.6 They did not evidence significant effects in use of analgesics. By contrast, Thijs et al. (2019) found that patients in the cryotherapy group used 2.6 times less opioids as an escape medication during the first four postoperative days compared to the control group. Although they found a significant reduction in NRS pain scores before and after cooling in the cryotherapy group, no clear differences on pain between the two groups in the first postoperative week were found. In the long-term too - 2, 6 and 12 weeks postoperatively - no differences could be evidenced. Our recently

published RCT has shown that computer-assisted cryotherapy during the first postoperative week following TKA has beneficial in terms of pain reduction and diminished opioid consumption during this first week. At 6 weeks no differences in pain were found. Also the physical examination tests - aROM, knee circumference and Timed Up and Go - showed no difference between groups after 6 weeks. A period of only one week cooling postoperatively can be a reason for short term beneficial effect of the cryotherapy. To our knowledge, no study has been conducted on the effects of 6 weeks cryo and compression therapy after a TKA and UKA.

There are several ways to apply cryotherapy, using ice or cold packs, or mechanical devices which create a standardized cooling treatment of the injured tissue, with and without compression. A review of the currently available literature in TKA patients (14 studies) and UKA patients (2 studies) stated that standardized continuous cold flow with compression was associated with better outcomes. However, since the financial aspect is also a major element in patient care, cost-effectiveness must be considered as well. Cost benefit analyses demonstrated that simpler devices as ice bag compression bandages or cold packs are far less costly, with no disadvantage in outcomes in several studies This makes that in the current study an easy-to-use brace with an inserted cold pack, that can be applied with a close fit to the knee, with optional application of manual compression will be used. The combination of cold and compression was suggested to result in longer and improved anaesthetic effect after application.

Study objective

Primary objective:
Investigating the effect of the use of cryo- and compression therapy during the first 6 postoperative weeks after surgery (TKA en UKA) on the perceived pain in rest at 6 weeks postoperative.

Secundary objectives:
Investigating the effect of the use of cryo- and compression therapy during the first 6 postoperative weeks after TKA/UKA surgery on pain in rest and while loading/during activity, oioid use, during the first 6 weeks, functioning, patient satisfaction, general health. Considering the differences in the rehabilitation between the patient groups (TKA and UKA), potential differences in effectiveness of the cryo- and compression intervention between both patient groups (UKA and TKA) on these outcome measures will be studied as well. Also the compliance will be monitored as a secundary outcome.

Study design

A single-centre single-blinded randomized controlled trial, executed in TKA and UKA patients.

Intervention

For the cryo and compression therapy the U-sport Ultimate Recover Knee cold compression brace (https://www.u-sport.com/producten/medical-care/ultimate-recover-knee/) will be used. This brace combines cold and compression therapy using a reusable gel package and an adjustable hand pump, which is an easy-to-use. Cryo and compression therapy will be administered during the first 6 postoperative weeks, starting after discharge. Because of practical reasons, no cryo- and compression therapy will be administered during admission. Patients will be instructed to use the brace 5 times a day for a maximum of 20 minutes, and will be advised to apply compression (amount of compression based on their own preference).The control group will receive standard post-operative treatment according to local rapid recovery rehabilitation program without the use of cryo and compression therapy. (Additional) use of a cold pack which is part of standard care is allowed in both groups.

Study burden and risks

Several studies have shown beneficial effects of 1 week of cryo- and compression therapy after TKA on pain reduction and diminished analgesic use in the first post-operative week. It is currently unknown what the effect of 6 weeks of cryo- and compression therapy will be on TKA/UKA rehabilitation. Possible benefits of this study are effective postoperative pain control, diminished use of opioid analgesic, improving functional outcome and patient satisfaction after TKA/UKA. Potential risks of cryotherapy are local hypothermia of the skin resulting in frostbite, necrosis and thrombosis. However, based on the current literature, these side effects were not reported in the studies using cryo- and compression therapy. To nullify these risks in our study, patients are instructed to wear the brace for a maximum of 20 minutes per cry-and compression session. In addition, patients are advised to put a piece of fabric cloth between the brace and the skin. We believe this makes the risks neglectable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Patients scheduled for a primary TKA or UKA in the Martini Hospital.
- age >= 18 years

Exclusion criteria

Exclusion criteria are:
- per-operative switch from UKA to TKA (only for the UKA patients),
- revision TKA implant (only for the TKA patients),
- rheumatoid arthritis,
- other co-morbidities on which cooling may have a negative effect on (based on judgement of the orthopaedic surgeon),
- inability to read and understand the Dutch language.

Because the cool pack needs to be cooled in a freezer, it is required that a patient or the nursing home has a freezer that can be used.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2023
Enrollment:	208
Type:	Actual

Medical products/devices used

Generic name:	cryo and compression brace
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-03-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05572359
CCMO	NL81956.100.22