Computer controlled cooling aftercare in patients with total knee arthroplasty

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Primary Objective: The primary objective of this study is to assess the efficacy of computer controlled cooling on postoperative pain in rest in the first 7 days of recovery, measured with the NRS score. Secondary Objectives: * Assess the effect of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON46091

Source
ToetsingOnline

Brief title
CCC 2016

Condition

- Bone and joint injuries

Synonym
postoperative pain // consumption of analgesics

Research involving
Human

Sponsors and support

Primary sponsor: Orthopedium
Source(s) of monetary or material Support: Orthopedium

Intervention

Keyword: Arthroplasty, cooling, cryotherapy, knee

Outcome measures

Primary outcome

The primary objective of this study is to assess the efficacy of computer controlled cooling on postoperative pain in rest in the first 7 days of recovery, measured with the NRS score.

Secondary outcome

* Assess the effect of compute controlled cooling on the use of analgesics.

* To compare the overall quality of life in patients with regular aftercare combined with computer controlled cooling to patients with regular aftercare. The Quality of Life will be measured by using standardized questionnaires being: EQ-5D, NRS for patient satisfaction, KOOS-ps and a OKS. These scores are discussed in detail in appendix

* Range of motion of the affected knee compared with the healthy knee

Study description

Background summary

Cooling of the joint is a proven modality in the postoperative treatment of pain and swelling after a total knee arthroplasty.
An abundance of applications exists, yet the most used options are (reusable) icepacks, bags of frozen peas as well as computer controlled cooling devices. As of yet, several reviews have not succeeded in pointing out the most effective method. Smaller studies have pointed out several advantages of computer controlled cooling: effective reduction of pain and therefore a smaller intake of analgesics (most notably morphine-derivates, resulting in lesser post-operative nausea and vomiting). A better range of motion and lesser swelling as well as improved patient wellbeing are other great advantages of

efficient application of computer controlled cooling1 (compared to the current conservative therapy with analgesics and icepacks).

The Zamar ZT Cube is a medical device based on heat exchange for cryotherapy and thermotherapy. With an anatomical knee wrap adjusted to the patient*s knee, cryotherapy is offered using continuous-cold flow through the pad during several cooling sessions per day. In the first seven post-surgery days, cryotherapy is applied to the post-operatively often swollen and inflammated joint. It has been suggested that the reduction in swelling as well as a more mildly occurring inflammatory reaction result in lesser pain, smaller intake of analgesics with its accompanying side effects as well as better patient satisfaction.

With this study we want to assess the efficacy of computer controlled cooling in the aftercare in patients who underwent primary total knee arthroplasty in addition to our regular aftercare.

Study objective

Primary Objective:
The primary objective of this study is to assess the efficacy of computer controlled cooling on postoperative pain in rest in the first 7 days of recovery, measured with the NRS score.

Secondary Objectives:
* Assess the effect of compute controlled cooling on the use of analgesics.
* To compare the overall quality of life in patients with regular aftercare combined with computer controlled cooling to patients with regular aftercare. The Quality of Life will be measured by using standardized questionnaires being: EQ-5D, NRS for patient satisfaction, KOOS-ps and a OKS.
* Range of motion of the affected knee compared with the healthy knee
* NRS-pain in activity

Study design

The chosen study design is a parallel study. Two groups of patients will receive either regular aftercare (physical therapy, analgesics) combined with computer controlled cooling or regular aftercare combined with regular cooling therapy (icepacks). During the first seven postoperative days, patients will be followed up in both clinical and out-patient setting.

Since there is no means of blinding the computer controlled cooling therapy, it is not possible to create a double-blind study. The amount of time and preparation required for a computer controlled cooling treatment prohibits randomized treatment assignment. However, the approach of patients is unbiased and purely based on their planned surgery (a weekly alternating scheme will be

in effect: patients in even numbered weeks will receive computer controlled cooling, patients in odd numbered weeks will receive regular aftercare or vice versa).

Intervention

Patients will receive - in addition to our regular medicinal aftercare * computer controlled cooling of the operated joint using the Zamar ZT Cube. For several hours per day the knee will be cooled to a temperature between 10 and 12 degrees Celsius using the thermal pad.
On the day of surgery, patients will be cooled for 6 hours postoperatively, followed by a 4 hour evening session and a 4 hour nightly session. At least 2 hours are in between every cooling session.
The first postoperative day, a 2 hour morning and 2 hour afternoon cooling session are followed by a 4 hour evening and an optional 4 hour nightly session. This scheme is continued unto day 7, however from day 2 the nightly cooling session is optional.

Study burden and risks

Risks: negligible
Burden: during the first seven postoperatieve days a total time of 74 hours of cooling of the joint on which surgery was performed. During the first seven days four times daily patients will register their NRS-pain and consumption of analgesics.

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

primary total knee arthroplasty

Exclusion criteria

Diabetes mellitus type II
Hypersensitivity to cold
Raynaud's phenomenom or disease
Arthroscopic surgery on same joint less than 3 months ago

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-02-2017
Enrollment:	126
Type:	Actual

Medical products/devices used

Generic name:	Zamar ZT Cube
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-12-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	09-01-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL56774.098.16