The effect of Computer-assisted Cryotherapy (CAC) on pain and narcotic consumption after TKA
A prospective dubbel blind randomized controlled study

Published: 07-10-2015
Last updated: 15-05-2024

To assess the effect of CAC with effective temperature on pain sensation and consumption of narcotics in patients operated for TKA after 7days postoperative compared to CAC without effective temperature.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON42616

Source
ToetsingOnline

Brief title
CAC after TKA

Condition

- Joint disorders

Synonym
Post operative pain and narcotic consumption

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: t onderozek wordt niet gefinancierd. Het is standaard!

Intervention

Keyword: Computer assisted Cryotherapy, TKA

Outcome measures

Primary outcome

Pain sensation of the operated joint, measured with a Numerical Rating Scale (NRS, 0 to 10, 10 being *worst pain*), before TKA and daily on fixed time points in a Pain diary including analgesic use measured as tramadol consumption as equianalgesic amounts.

Secondary outcome

* Knee range of motion (ROM), measured as degrees of active knee flexion and extension evaluated with the use of a handheld goniometer.

* Swelling (measured as circumference in millimeters at two fixed points of the knee at the same time of day at different stages postoperatively, 10 cm superior to the patella and 10 cm inferior to the patella and then the average was divided by two and expressed in millimeters)

* Visual hematoma (yes/no)

* Patient reported outcome measures (PROMS) including WOMAC and Oxford Knee Score. Furthermore, quality of life will be assessed with the EuroQoL-5D questionnaire.

Study description

Background summary

External application of cold therapy in the proximity of joints is an old but poorly investigated treatment modality for postoperative pain. It has been shown that it can decrease swelling and can thus possibly reduce local pain sensation. Despite all that, on closer consideration the universally valid consensus of the optimal methods regarding locally applied cryotherapy after TKA is still clearly missing. Therefore, we will investigate the effect of locally applied Computer-assisted Cryotherapy (CAC) on pain sensation and consumption of narcotics in patients who are operated for total knee arthroplasty (TKA) following an outpatient surgery pathway. These patients will be discharged on the day of surgery, and will have theyre own CAC-system at home.

Study objective

To assess the effect of CAC with effective temperature on pain sensation and consumption of narcotics in patients operated for TKA after 7days postoperative compared to CAC without effective temperature.

Study design

Prospective, randomized placebo controlled trial with two arms:
* arm 1: CAC with effective temperature
* arm 2: CAC without effective temperature

Intervention

CAC of the operated knee, given on post operative day 0 upto day 7with or without effective temperature
.

Study burden and risks

Cryotherapy was generally safe and not associated with any serious adverse events.

Contacts

Public
Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1
Sittard-Geleen 6162 BG
NL
Scientific
Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1
Sittard-Geleen 6162 BG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Patients scheduled to undergo primary TKA replacement with any of the following indications
-Painful and disabled knee joint resulting from osteoarthritis.
-High need to obtain pain relief and improve function,
-Above 18 years old.
-Body-mass-index (BMI) <35
-Ablility and willingness to follow instructions, including control of weight and activity level, and to return for follow-up evaluations.
-Consent form read, understood and signed by patient.

Exclusion criteria

-Active infection in knee
-General infection
-Distant foci of infections which may spread to the implant site
-Failure of previous joint replacement
-Pregnancy
-Previous major knee surgery, except for arthroscopic meniscectomy.

-Metal near knee joint (MRI-scan not possible)
-Not able or willing to undergo MRI-scan or CT-scan
-Reumatoid arthritis
-Non-correctable varus axis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2015
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Computer assisted Cryotherapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	07-10-2015
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23301
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54641.096.15
OMON	NL-OMON23301