Het effect van computer gestuurde koeltherapie op de pijn beleving en het gebruik van morfine houdende medicatie na plaatsing van een totale knieprothese
Een prospectieve gerandomisserde placebo gecontroleerde studie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23301

Source
NTR

Brief title
Koeltherapie na plaatsing van een totale knieprothese

Health condition

Patients with painful osteoarthritis of the knee who present themselves at the orthopedic outpatient clinic of Zuyderland Medical Centre, loction Sittard-Geleen

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

To determine the effect of CAC on pain sensation and consumption of equianalgesics upto 7 days postoperative after TKA. Pain measured with a Numerical Rating Scale (NRS)

Secondary outcome

• To determine the effect of CAC on knee range of motion (ROM), measured as degrees of active knee flexion and extension evaluated with the use of a handheld goniometer.

• To investigate the effect of CAC on knee 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)

• To investigate the effect of CAC on visual hematoma (yes/no)

• To determine the effect of CAC on patient reported outcome PROMS including WOMAC and Oxford Knee Score. Furthermore, quality of life will be assessed with the EuroQoL-5D questionnaire.

Study description

Background summary

Even though some studies show excellent results regarding CAC, this treatment, the quality of the available literature is not convincing and level I evidence is still missing. Cryotherapy was generally safe and not associated with any serious adverse events and may improve the range of motion at the knee in the first one to two weeks after surgery. No studies were found that looked at the effects of cryotherapy on a person’s activities related to knee function. Well designed randomised trials are required to improve the quality of the evidence

Study objective

Our hypothesis is that CAC can achieve a pain-reducing effect of at least 20% after 7 days.

Study design

pre- and 7 days and 2 and 6 weeks post-operatively

Intervention

The patients will be discharged to home after TKA on the day of surgery. At home the joint, will be cooled using CAC during a period of 7 days according to our protocol. Patients will receive 6 hours of continuous cooling at 8°C immediately after surgery (starting in their room). In the evening (12°C) and during the first night at home (12°C), patients will receive 4 hours each of CAC.

The day after surgery the protocol consisted of 2 hours of treatment in the morning (10°C), followed by 2 hours of CAC in the afternoon (10°C). During the second evening and nights, patients will receive one session of 4 hours each (12°C). The next nights patients are allowed to use CAC as option in case of extreme pain (12°C). The second day postoperative the protocol consisted of 2 hours of treatment in the morning (10°C), followed by by 2 hours of CAC in the afternoon (10°C), this schedule will be repeated up to postoperative day 7. The night sessions are optional in case of extreme pain (12°C). A minimum of 2 hours must be wihtin the sessions.

Contacts

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Eligibility criteria

Inclusion criteria

•Patients scheduled to undergo primary TKA replacement

•No previous surgery on the operated knee except open meniscectomy

•Ability and willingness to follow instructions and to return for follow-up evaluations

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

•Rheumatoid arthritis

•Extension deficit of more than 15 degrees

•Flexion less than 110 degrees.

•Non-correctable varus axis

•Cruciate ligament insufficiency

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-10-2015
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-11-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42616
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5431
NTR-old	NTR5565
CCMO	NL54641.096.15
OMON	NL-OMON42616

Study results