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

Gepubliceerd: 03-11-2015 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23301

Bron
NTR

Verkorte titel
Koeltherapie na plaatsing van een totale knieprothese

Aandoening

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

Ondersteuning

Primaire sponsor: NA
Overige ondersteuning: NA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

•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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

•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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-10-2015
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-11-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42616
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten