Fast Track Recovery with Bioheat Transfer in Knee Revision-prosthesis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36903

Source
ToetsingOnline

Brief title
Bioheat Transfer in Knee Revisions-prosthesis

Condition

- Joint disorders

Synonym
inflammation, postopertive recovery

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Thermomend;Nobelstraat 10 t/m 14;5807GA;Oostrum Netherlands;Attention: Rene Richters;Director

Intervention

Keyword: Bioheattransfer, cryotherapy, cTreatment, knee revision

Outcome measures

Primary outcome

Primary Objective:

Increase of Flexion in the group of patients receiving cTreatment

Secondary outcome

Secondary Objective(s):

1.) reduced opioids consumption postoperative

2.) reduced Pain in the VAS-score

3.) reduced swelling postoperative (5th day)

Study description

Background summary

This trial is meant to verify a new medical method (computer controlled bioheat transfer) to reduce pain and swelling and optimize early mobilisation following knee replacement revision surgeries. Most likely because of greater soft tissue trauma functional outcome after revision knee arthroplasty is not that good as after primary knee arthroplasty. [1-5] To reduce the inflammatory reaction caused by the soft tissue trauma during the operation, cryotherapy is used postoperatively.

At the Department of Orthopaedics Surgery OLVG Amsterdam, currently, cold packs (koud en warm pak, ENRAF-NONIUS B.V. P.O. Box 12080 3004 GB Rotterdam, the Netherlands; CE 65.0103002.12, LA 3448209) are used for cryo-therapy to reduce postoperative pain and swelling. The cold packs are used twice a day for twenty minutes each time. Cooling the operative wound with this method shows positive effects, but the method offers a great room for improvement: at the beginning of the treatment with cool packs the temperature is too cold (sometimes below zero degrees - depending on the temperature of the freezer, which could well be -18 degrees), with the risk to complications and little comfort to the patient and after a short time the packs are getting too warm (body temperature),

because of which no long and deep cooling is possible.
A new approach to attain better results is a new computer-controlled bioheat transfer platform, named cTreatment. The class 2a medical device provides a controlled, continuous, stable and predefined temperature at the affected site (the operated knee in this trial) and guaranties an optimal tissue temperature drop, not only superficially but also in depth. Optimizing the tissue temperatures and thereby lowering the postoperative inflammatory reaction, both superficial as in depth, over a longer period is expected to reduce swelling and pain, whereby patient's postoperative mobilization can be started earlier and be done more efficiently, leading to a reduction of the length of hospitalization.
The cTreatment Technology server based Platform has embedded the complex phenomena of Bio Heat Transfer to control the parameters within the thermodynamic model. Bio Heat Transfer is a dynamic process that analyses transport of heat by conduction, convection and radiation, as well as by temperature dependent, spatially heterogeneous blood perfusion in living organisms with conventional mathematical models (Pennes' equation, Che and Holmes new bioheat equation) and numerical techniques (continuum bio-heat transfer in three dimensional anatomical structures). From a thermal point of view, biological systems consist of a complex network of blood vessels which convect heat and are embedded in tissue. The tissue is inhomogeneous and at times anisotropic with complex thermal properties. It also produces heat as part of the life and of pathological (e.g. inflammation) metabolism. All these aspects of a living organism make mathematical models of heat transfer complex. The standardized, computer controlled cTreatment® protocols incorporate thermodynamic bio heat transfer with the body, based upon scientific and reproducible protocols. Through indication specific protocols and by using active feedback, it enhances the positive healing effects of inflammatory processes and reduces the destructive effects of inflammation, allowing the medical professional more complete and direct control of the recovery process. cTreatment has both triggering and synergetic effects on most of the physiological parameters of inflammation and trauma:

In the Department of Orthopaedic Surgery of the OLVG currently postoperative hospitalization after revision of a knee-prosthesis takes 14 to 18 days on average. It is an international aim to reduce the duration of postoperative hospitalization (reduction of costs). Since optimizing in prosthetic design is rarely possible as it*s already that well engineered, it*s worthwhile to focus on postoperative soft tissue management in further investigations.
In pursuance of previous experience, cryotherapy influences patients* postoperative mobilisation positively. [6-8]

The aim of the study is to compare cTreatment with the standard cooling protocol (cool packs) used at the Department of Orthopaedics Surgery OLVG in patients with revision procedures after a previous primary total knee arthroplasty. We expect, that patients treated with cTreatment need less pain medication, show reduced swelling and a quicker recovery to full flexion

compared with patients treated with conventional superficial cryotherapy with cold packs.
This pilot study will be done in cooperation with the Department of Orthopaedic Surgery, Medical University of Graz.

Study objective

To compare the methods patients will be divided into two groups, a therapy group (receiving cTreatment) and a control group (receiving standard cryotherapy). Patients will be evaluated pre- and postoperatively, wherefore the following data are collected: the knee flexion, swelling (in centimetres), laboratory parameters (standard parameters) clinical evaluation scores and psychological parameters (using standardised questionnaires) as well as the AAOS discharge criteria.
The collected data shall be analysed to show any difference between cTreatment (computer controlled bioheat transfer) and the standard short period superficial cooling therapy following implantation of a revision knee endoprostheses.

Study design

Multi center, double-blind randomized placebo-controlled pilot trail.

Study centers:
OLVG Amstedam
Medical University of Graz

Duration: 12 Month

Study burden and risks

Our hypothesis is that c-Treatment improves range of motion, reduces postoperative swelling of the knee and that pain scores are lower. We also expect that the length of stay will be reduced. Because the contact temperature is never below 8 degrees Celsius there is no risk for cryo-lesions or burn lesions. There is also no higher risk for thromboses, infections or other adverse events. Since the first use of cTreatment no adverse events were reported, besides a few blisters, which could not be directly related to the use of cTreatment. The 2 patients in whom they occurred had also used ice-bags during their hospital stay, which are a known risk to frostbite.
During three pilot studies (total 59 patients) no adverse events were reported. In one of these studies cTreatment was even applied during 12 hours of continuous use on 10 patients. Furthermore in the recent comparative cohort trial in the AMC in Amsterdam no adverse events were reported on the 31

patients who received cTreatment for primary total knee arthroplasty.

Contacts

Public
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1091 AC
NL
Scientific
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1091 AC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age: 18 - 90 years
Implantation of a semi-constrained or constrained knee prosthesis in the course of
- revision procedures as: explantation of primary total knee prosthesis or spacer explantation and implantation of semi-constrained knee prosthesis
- instability (primary and secondary knee replacement)
Written informed consent

Exclusion criteria

Body Mass Index greater than 40
Cold urticaria, cryoglobulinemia, paroxysmal cold hemoglobinuria
Acute fracture, infection or tumour at the affected knee
Cold allergy or cold intolerance
Raynaud's Disease
Circulatory disorder at affected site (e.g. PAD, Diabetic foot)
Fibromyalgia or other chronic pain syndromes
Drug or alcohole abuse
Pregnancy or possible pregnancy without adequate contraception
No written informed consent
Unsoundness of mind

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	CTreatment
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-11-2012
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
CCMO	NL40847.100.12