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Effectiveness of continuous passive motion (CPM) in the early post total knee arthroplasty period, as an adjunct to physiotherapy

Submission date
17/03/2014

Recruitment status
No longer recruiting

Registration date
12/06/2014

Overall study status
Completed

Last Edited
12/06/2014

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Continuous passive motion (CPM) is used as a part of the rehabilitation of patients who have undergone total knee arthroplasty (TKA). CPM has been widely used as an add on to physiotherapy after TKA for the past two decades. However, there is still controversy as to whether it is useful. The range of motion (ROM) has been reported to improve as a result of CPM. On the other hand, other studies have found no statistically significant change in ROM. Among the proposed benefits of CPM is the reduction of pain after the operation. There is a lot of debate about the duration of individual sessions of CPM. The aim of this study is to find out whether and how CPM is helpful after total knee arthroplasty. It will also examine whether the application time (30 min vs 60 min) of the CPM device affects pain and the knee joints active ROM soon after the operation.

Who can participate?
Men and women (age 5080 years) who will undergo total knee arthroplasty in the 1st Orthopaedic Department of the KAT General Hospital of Athens.

What does the study involve?
Participants will be randomly divided into three groups. The control group will be treated with physiotherapy. The CPM-30 group will be treated with physiotherapy combined with the application of a CPM device for 30 minutes twice a day. The CPM-60 group will be treated with physiotherapy along with the application of a CPM device twice a day, but for 60 minutes. The use of CPM will start on the second day after the operation.

What are the possible benefits and risks of participating?
Participants will receive physiotherapy regardless of the procedure to be performed. All patients will receive a better or a faster rehabilitation program. Information obtained from this study may benefit patients undergoing total knee arthroplasty in the future. Participation in this study will not increase the rate of possible postoperative complications.

Where is the study run from?
1. Physiotherapy Department of the Technological Educational Institute of Athens (TEI of Athens), Greece
2. First Orthopaedic Department of the KAT General Hospital of Attica, Greece.

When is the study starting and how long is it expected to run for?
The study started in November 2012 and will run until the required number of patients has been evaluated.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
271/05-11-2012

Study information

Scientific Title
Continuous passive motion (CPM) in the early postoperative period following total knee arthroplasty: effect on pain and active motion

Study objectives

The use of CPM combined with physiotherapy in early postoperative rehabilitation after total knee arthroplasty (TKA) will produce more beneficial results than physiotherapy alone, with the degree of added benefit being related to the duration of CPM application.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee of the Technological Educational Institute of Athens, ref: 1/15-02-2013; 15/02/2013
2. Scientific Research Council of the 'KAT' General Hospital of Athens, ref: 271/05-11-2012

Study design
Randomized parallel group clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Total knee arthroplasty rehabilitation protocols

Interventions
Participants will be divided into three groups.
1. The control group will follow only the conventional physiotherapeutic protocol
2. The CPM-30 group will follow the same physiotherapeutic protocol combined with two 30-min daily sessions of CPM
3. The CPM-60 group will follow the physiotherapeutic protocol in conjunction with two 60-min daily sessions of CPM

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Difference in postoperative pain and knee range of motion (ROM) according to the CPM application duration. Pain was evaluated by the patient, with the Greek version of the VAS/FPS-R

pain scale (self-reported measure) and the range of motion was measured with two identical, long-arm goniometers by two researchers and the average of the two values was recorded (objective measure).

Secondary outcome measures
1. At 7th postoperative day, the acquired active ROM (knee flexion and extension)
2. Evaluation of postoperative pain (2nd and 7th postoperative days)

Baseline data and demographic characteristics were measured the day before surgery. Pain was measured twice (the 2nd and 7th postoperative day). The active range of the flexion motion and the extension motion were measured on the 7th postoperative day.

Overall study start date
12/11/2012

Completion date
17/03/2014

Eligibility

Key inclusion criteria
1. Age 5080 years
2. All participants must be ambulatory and must not have undergone any osteotomy or arthroscopy in the joint of interest during the last 12 months
3. Willing to be assigned to any of the three study intervention groups

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Total target number: 75 participants (Each group will include 25 participants)

Key exclusion criteria
1. Patients who have rheumatoid arthritis, musculoskeletal diseases, diabetes, or peripheral vascular disease
2. Patients undergoing treatment with corticosteroids
3. After enrollment, patients will be excluded if they present:
3.1. Postoperative complications, such as problems in incision healing
3.2. Pulmonary embolism

Date of first enrolment
12/11/2012

Date of final enrolment

17/03/2014

Locations

Countries of recruitment
Greece

Study participating centre
30 Ouranias Street
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Sponsor information

Organisation
KAT" General Hospital of Athens (Greece)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04prmqc97

Funder(s)

Funder type
Other

Funder Name
Investigator intiated and funded (Greece)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration