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Effectiveness of prolonged use of continuous passive motion (CPM) as an adjunct to physiotherapy following total knee arthroplasty (TKA)

Submission date
26/08/2005

Recruitment status
No longer recruiting

Registration date
07/09/2005

Overall study status
Completed

Last Edited
14/09/2017

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effectiveness of prolonged use of continuous passive motion (CPM) as an adjunct to physiotherapy following total knee arthroplasty (TKA)

Study objectives
What is the effect on range of motion and functional status of prolonged use of a continuous passive motion device at home in addition to physical therapy, compared to physical therapy alone, in patients with limited flexion range of motion (less than 80°) of the knee at discharge from the hospital following total knee arthroplasty?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet

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

Interventions
Physical therapy versus physical therapy + continuous passive motion

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Functional status and range of motion

Secondary outcome measures
Perceived effect, postoperative medication use, satisfaction with treatment, satisfaction with treatment result, adherence to treatment protocols and use of CPM (in hours)

Overall study start date
01/04/2005

Completion date
01/10/2006

Eligibility

Key inclusion criteria
Patients with knee osteoarthritis (OA) undergoing TKA and experiencing early postoperative flexion impairment (less than 80° of knee flexion at the time of discharge).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Key exclusion criteria
Patients will be excluded if they need to stay in hospital for more than 5 days after surgery or show relevant co-morbidity influencing mobility (e.g. claudication, other prosthesis) or are operated upon using minimally invasive surgery.

Date of first enrolment
01/04/2005

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
Netherlands

Study participating centre

University Hospital Maastricht
Maastricht
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6229 HX

Sponsor information

Organisation
University Hospital Maastricht (The Netherlands)

Sponsor details
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Sponsor type
University/education

Website
http://www.azm.nl

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
University/education

Funder Name
University Hospital Maastricht (Netherlands)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2003		Yes	No
Protocol article	protocol	23/02/2006		Yes	No
Results article	results	29/04/2008		Yes	No