PaTIO study : PhysiotherApeutic Treat-to-target Intervention after Orthopaedic surgery; A cost-effectiveness study.

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To evaluate the cost-effectiveness of optimized, treat-to-target PPT in TKA/THA patients as compared to usual PPT. Thehypothesis is that with the optimized strategy superior functional outcomes can be achieved compared to usual care, at lowercosts (...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON55756

Source
ToetsingOnline

Brief title
PATIO study

Condition

- Joint disorders

Synonym
hip and knee replacement; total hip and knee arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Leading the Change call (Zorgverzekeraars)

Intervention

Keyword: postoperative physiotherapy, THA, TKA, treat-to-target

Outcome measures

Primary outcome

Difference between both groups regarding changes of KOOS-PS/HOOS-PS, a measure

of physical functioning, between

baseline and 3 months postoperatively.

Differences between both groups regarding cost-effectiveness.

Secondary outcome

Differences between both groups in:

- recovery of function during 12 months follow-up,

- in scores of OKS/OHS (functioning), NRS (amount of pain), EQ-5D (quality of

life), performance tests, physical activity level, and satisfaction of the

patient.

Study description

Background summary

Postoperative physiotherapy (PPT) is a proven effective treatment after total knee (TKA) and hip arthroplasty (THA), however research shows that there is no consensus regarding its timing, content and duration and practice variation is considerable. We propose an evaluation of optimized, personalized treat-to-target PPT, which is presented in the form of a transmural care pathway.

Study objective

To evaluate the cost-effectiveness of optimized, treat-to-target PPT in TKA/THA patients as compared to usual PPT. The

hypothesis is that with the optimized strategy superior functional outcomes can be achieved compared to usual care, at lower costs (superiority study).

Study design

Cluster randomized study

Intervention

Treat-to-target: optimized, personalized strategy implying that after receiving PT in the postoperative phase in the hospital will either or not be referred to primary care PT based on a standardized assessment of their health status, personal-, external factors and achievement of functional milestones. Those needing PPT in primary care receive a standardized, time contingent program, focused on evidence-based components muscle strengthening and functional exercises, with regular evaluations regarding achievement of functional milestones. After reaching the milestones, PPT is ended and patients will receive a tailored advice with home-based exercises in combination with referral to exercise activities in the community. The treat-to-target PPT is based on scientific evidence and expert opinion and is presented in the form of a transmural care pathway.
Usual care: Current PPT delivery

Study burden and risks

Patients will be asked to fill out questionnaires at 6 time points (at home, web-based program). At three time points the patients will be asked to perform physical performance tests. So additional time will be asked from the participating patients. In our view patients participating in this study will undergo no additional risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients eligible for this trial are patients with clinical and radiological knee or hip OA who are scheduled for a primary TKA or THA, and willing to comply with the study protocol.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: TKA or THA for a diagnosis other than OA, uncontrolled cardiovascular disease or hypertension, history of neuromuscular disorder that affects lower extremity function, terminal illness, plans to have another joint replacement during study follow-up, not able to attend follow-up measurements, not able to attend the PPT in primary setting, serious adverse events during surgery or directly thereafter, serious psychiatric disorders, or insufficient command of the Dutch language, spoken and/or written.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2018
Enrollment:	624
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-04-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-04-2018
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-11-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-04-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-06-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27356
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61763.078.17
OMON	NL-OMON27356