

Kwaliteit van leven na plaatsing van een knie prothese bij dag-opname.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20339

Source

NTR

Brief title

HRQ-TKA_OS

Health condition

Patients with osteoarthritis initiated for knee arthroplasty

Sponsors and support

Primary sponsor: Zuyderland MC

Source(s) of monetary or material Support: n.a.

Intervention

Outcome measures

Primary outcome

Health-Related Quality of Life

Secondary outcome

other PROMs:

Oxford Knee Score (OKS; 12 to 60, 12 being the best outcome) [Haverkamp et al. 2005] and the Western Ontario and McMaster Universities Arthritis Index (WOMAC; 0 to 100, 100 being the best outcome) [Roorda et al. 2004]. Experienced pain was measured by a Numerical Rating Scale (NRS, 0 to 10, 10 being 'worst pain').

Study description

Background summary

Modification of a selected number of literature-based protocols, used together, can be implemented in a care pathway. Such optimization is also known as 'outpatient joint arthroplasty', a multimodal clinical pathway based on well-defined patient selection criteria.

With the present case-controlled study, we want to analyze if the OS pathway will result in comparable or better outcomes compared to our standard pathway (ERP) if it becomes to Health-Related Quality of Life as measured with the EQ-5D PROMs.

Study objective

It was hypothesized that there would be no difference in quality of life between both pathways.

Study design

preoperative, 3- and 12-months postoperative

Intervention

enhanced recovery pathway

outpatient joint arthroplasty

Contacts

Public

Department of Orthopedic Surgery, Zuyderland Medisch Centrum dr H vd Hoffplein 1
M.G.M. Schotanus
Geleen 6162 BG
The Netherlands
+31 (0)88 4597823

Scientific

Department of Orthopedic Surgery, Zuyderland Medisch Centrum dr H vd Hoffplein 1
M.G.M. Schotanus
Geleen 6162 BG
The Netherlands
+31 (0)88 4597823

Eligibility criteria

Inclusion criteria

- o Operated between June 2014 and June 2015
- o Elective primary knee arthroplasty

Exclusion criteria

- o Incomplete registration of data
- o Acute or revision arthroplasty surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2017
Enrollment:	361

Type: Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date: 09-02-2017

Application type: First submission

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
NTR-new	NL6248
NTR-old	NTR6406
Other	NA : 16N194 METC

Study results

Summary results

Improved Health-Related Quality of Life after Knee Arthroplasty Following an Outpatient Surgery Pathway: an Observational Comparative Case Study

Martijn G. M. Schotanus, Yoeri F. L. Bemelmans and Nanne P. Kort

J Clin Trials 2017, 7:5. DOI: 10.4172/2167-0870.1000327