Early follow-up after TKA with rapid recovery, diary-study. A pilot study.

Published: 12-11-2013
Last updated: 22-04-2024

This study investigate the problems which patients experience after hospital discharge after TKA surgery during the first six weeks post-operative. We will use the outcome of this study to optimize the first six weeks after hospital discharge.The...

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

Summary

ID

NL-OMON40125

Source
ToetsingOnline

Brief title
Early follow-up after TKA with rapid recovery

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
cartilage degeneration, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Maatschap orthopedie. Er is subsidie aangevraagd bij de WAC (wetenschappelijke commissie van het RdGG) voor de kosten van de dagboekjes

Intervention

Keyword: Diary-study, Early follow-up, Rehabilitation, TKA

Outcome measures

Primary outcome

The selected questionnaires focused on pain, rehabilitation, physical and

mental functioning, medication, quality of life and complications.

Secondary outcome

not applicable.

Study description

Background summary

Historically, the length of hospital stay after primary Total Hip Arthroplasty (THA) and primary Total Knee Arthroplasty (TKA) exceeded several weeks, with a subsequent period of bed rest during hospitalization. During the last decade, there has been a continued interest in reducing the length of hospital stay to a few days. Moreover rapid recovery protocols have been introduced worldwide after elective primary THA and TKA. Various studies have shown these protocols have reduced the length of hospital stay and the length of rehabilitation following primary THA and TKA. Also a decrease in complication rate and readmission rate have been described.
These rapid recovery protocols are based on analysis of clinical care principles and pain management in combination with the revision of organizational factors, allowing an optimized perioperative period that is safe for the patient.
In Reinier de Graaf Hospital (RdGG), the introduction of the rapid recovery protocol for primary THA and TKA started in 2009 and was introduced in several phases. In February 2011 all phases of this rapid recovery protocol for primary THA were introduced. The introduction of the rapid recovery protocol in our hospital indeed yielded a shorter length of hospital stay without an increase of complications, readmissions and reoperations after primary THA and TKA.
Most studies on rapid recovery focused on optimizing the postoperative phase during hospital stay. However, little is known about the early postoperative phase after discharge from the hospital. Studies on outcome after hospital discharge mostly evaluate function after three to six month little is known of the first 6 weeks after discharge.

The focus of this study will be on problems regarding pain, rehabilitation, physical functioning, medication, quality of life and complications of patients after TKA surgery with rapid recovery during the first 6 weeks after discharge from the hospital.

Study objective

This study investigate the problems which patients experience after hospital discharge after TKA surgery during the first six weeks post-operative. We will use the outcome of this study to optimize the first six weeks after hospital discharge.
The focus of this study will be on problems regarding pain, rehabilitation, physical functioning, medication, quality of life and complications.

Study design

This a prospective, observational trail in which 30 patients are asked to complete questionnaires on daily basis the first 6 weeks after primary TKA surgery. We will call patients to remind and to motivate in the first 2 weeks 2 times and in the 3rd and 5th week one time by the research nurse. The completed questionnaire will be returned to the surgeon at standard 6 weeks control.

Study burden and risks

Patients will be asked to complete questionnaires on daily basis. This will take 5 minuts a day. During this 2 weeks the investigator / research nurse will call two times a week to motivate to complete the questionnaires.
During the 3rd to 6th week patients will be asked daily basis. This will take 4 minutes a day. In the 3rd and 5th week the investigator / research nurse will call to motivate.
Total effort for patients will be 3,5 hours during the six weeks.

There will be no risk for patients in this study.

Contacts

Public
Reinier de Graaf Groep

Reinier de Graafweg 3-11
Delft 2625AD
NL
Scientific
Reinier de Graaf Groep

Reinier de Graafweg 3-11
Delft 2625AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients aged 18 years and older
Primary total knee arthroplasty
Patients willing to participate
Speaking and writing Dutch language

Exclusion criteria

Patients unwilling to participate
mentally disabled patients
Patients with alcoholic and or drug abuse
insufficient command of the Dutch language
Patients participating in research in which a new prosthesis is studied

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	11-06-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL45040.098.13