The influence of Expectation modification in Knee arthroplasty on Satisfaction of PatiEnts, a randomized Controlled Trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25479

Source
NTR

Brief title
The EKSPECT study

Health condition

Knee Osteoarthritis, knie artrose, gonartrose,

Sponsors and support

Primary sponsor: Máxima Medical Centre, Eindhoven
Source(s) of monetary or material Support: Máxima Medical Centre , Eindhoven

Intervention

Outcome measures

Primary outcome

Patient satisfaction one year postoperative.

Secondary outcome

- To assess whether there is an effect on patient expectations concerning the results of TKA of a preoperative joint-specific educational module (intervention) compared to the usual information giving (control).

- Explorative analysis will be performed to assess whether the preoperative joint-specific education is more effective in subgroups of patients.

Study description

Background summary

Rationale: Despite the fact joint replacement of the knee is a very successful surgical intervention for patients with end-stage osteoarthritis, a subgroup of the patients is not satisfied with the final results. One of the main modifiable factors that are related to patient satisfaction is whether the expectations of the patients are fulfilled. Frequently a discrepancy exists between expectations of the patients and those of the surgeon regarding the outcome of a total knee replacement (TKA). It seems that surgeons have more realistic expectations regarding relief of pain, improvement in physical functioning and improvement in psychosocial well-being. Specific information about these topics could lead to more realistic patient expectations. The current preoperative information giving is predominantly focused on the process of care and the immediately postoperative period. This can be extended by giving preoperative education about the recovery of symptoms, physical functioning and psychological well-being.

In this randomised clinical trial 204 patients indicated for a TKA will be included and will be prospectively evaluated for 1 year.

Objective: The aim of this study is to examine whether a joint-specific educational module (preoperative education about the recovery of symptoms, physical functioning and psychological well-being (index group)) will improve patient satisfaction after TKA compared to usual information giving (control group).

The hypothesis is that a preoperative joint-specific educational module is more effective to increase the satisfaction rate of patients undergoing a joint replacement of the knee compared to the usual given information (superiority study).

Study design: a double-blinded randomized clinical trial.

Study population: Patients visiting an orthopaedic surgeon at the outpatient clinic of Máxima Medical Centre, with clinical and radiological knee osteoarthritis, indicated and planned for a

TKA are eligible for this study.

Intervention (if applicable): Patients will be randomized in a) a joint-specific educational module (preoperative education about the recovery of symptoms, physical functioning and psychological well-being (index group) or in b) the usual given information.

Main study parameters/endpoints: The primary outcome measure will be patient satisfaction with the 12 months results of TKA.

Study objective

A preoperative joint-specific educational module is more effective to increase the satisfaction rate of patients undergoing a joint replacement of the knee compared to the usual given information

Study design

Pre-operative, 3 months and 1 year postoperative

Intervention

Patients will be randomized in

a) a joint-specific educational module (preoperative education about the recovery of symptoms, physical functioning and psychological well-being (index group) or in

b) the usual given information.

Contacts

Public
Maxima MC
J.J. Tolk
Eindhoven
The Netherlands
0408888600
Scientific
Maxima MC
J.J. Tolk
Eindhoven

The Netherlands
0408888600

Eligibility criteria

Inclusion criteria

Symptomatic and radiographic knee OA indicated for a primary TKA

Exclusion criteria

Presence of a medical illness that result in a Life expectancy shorter than 1 year.

Presence of TKA of the contralateral side.

Insufficient command of the Dutch language.

Legally incompetent adults.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2016
Enrollment:	204
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	17-03-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42387
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5006
NTR-old	NTR5779
CCMO	NL54671.015.15
OMON	NL-OMON42387

Study results