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

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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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25479

Bron
NTR

Verkorte titel
The EKSPECT study

Aandoening

Knee Osteoarthritis, knie artrose, gonartrose,

Ondersteuning

Primaire sponsor: Máxima Medical Centre, Eindhoven
Overige ondersteuning: Máxima Medical Centre , Eindhoven

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient satisfaction one year postoperative.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Pre-operative, 3 months and 1 year postoperative

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Symptomatic and radiographic knee OA indicated for a primary TKA

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2016
Aantal proefpersonen:	204

Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies
Datum: 17-03-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42387
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten