PATRES: Una patella particulare.

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Patella resurfacing in patients with symptomatic knee OA who are indicated for total knee replacement and show clinically and radiologically signs of patellofemoral OA will give an improvement of the Baldini score > 10% (after TKA) compared to...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25294

Bron
Nationaal Trial Register

Verkorte titel
PATRES

Aandoening

Patellar resurfacing, patellaprothese, knieschijfvervanging

Ondersteuning

Primaire sponsor: Martini Hospital, Department of Orthopaedic Surgery
Overige ondersteuning: Martini Hospital, Department of Orthopaedic Surgery

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of the study is to evaluate if patients undergoing resurfacing of the patella during TKA show at least 10 % improvement in the Baldini score (after 18 months) compared to patients undergoing TKA without resurfacing of the patella.

Hypothesis:
Patella resurfacing in patients with symptomatic knee OA who are indicated for total knee replacement and show clinically and radiologically signs of patellofemoral OA will give an improvement of the Baldini score > 10% (after TKA) compared to patients without resurfacing the patella.

Toelichting onderzoek

Achtergrond van het onderzoek

Total knee arthroplasty (TKA) is a well-established surgical procedure effective in relieving pain and improving function in patients suffering from knee osteoarthritis (OA). However, it remains unclear whether the patella should be resurfaced during TKA. Resurfacing the patella is considered to lower the incidence of patellofemoral complaints after this procedure. Numerous studies have analysed the results and risks of patellar resurfacing. A meta analysis including 1223 knees showed a reduction in the absolute risk on postoperative anterior knee pain of 14% (95% confidence interval, 6% to 21%). Also, the risk of re-operation after resurfacing the patella is significantly lower. Other reports have demonstrated that re-operation for only patellar resurfacing after TKA leads to inferior results compared to initial patellar resurfacing during primary TKA.

Resurfacing the patella, however, is not without problems. Complications include patellar fracture, tendon rupture, osteonecrosis, overstuffing, and soft tissue impingement. Unsatisfactory results may also be caused by patellar tilt, maltracking, instability, polyethylene wear, and the patellar clunk syndrome.

According to most authors, indications for patellar resurfacing during primary TKA include: older age, anterior kneepain or other patellofemoral symptoms, rheumatoid arthritis (RA), obesity, history of patellar subluxation or dislocation, large and/or thick patellae, multi operated knee and major loss of patellofemoral articular cartilage noted intraoperatively. Current prospective reports fail to recognize any clinical outcome differences among patients after TKA with or without a resurfaced patella. Most studies use established clinical knee scoring systems, such as the Knee Society clinical rating system (KSS) and the Hospital for Special Surgery score (HSS). These scoring systems mainly focus on tibiofemoral aspects, whereas specific patellofemoral symptoms can be missed or underscored.

Recently, Baldini et al. published a validated scoring system specifically designed to evaluate the patellofemoral joint after total knee arthoplasty.

Furthermore, most studies have reported that when anterior knee pain develops, it occurs within the first 18 months after performing TKA. We hypothesize that patients with patellofemoral knee OA receiving TKA and patellar resurfacing will have significantly better clinical results using the Baldini scoring system compared to patients without patellar

resurfacing after 24 months.

Doel van het onderzoek

Patella resurfacing in patients with symptomatic knee OA who are indicated for total knee replacement and show clinically and radiologically signs of patellofemoral OA will give an improvement of the Baldini score > 10% (after TKA) compared to patients without resurfacing the patella.

Onderzoeksopzet

Radiological and clinical follow-up pre-operatively, 1 day after operation, then after 6 weeks, 6, 12, 18 en 24 months.

Onderzoeksproduct en/of interventie

Single- blinded randomized controlled trial. Patients suitable for enrollment in the study are patients who show clinically and radiologically signs of patellofemoral OA and are candidates for total knee replacement. Patients will undergo patellar resurfacing, denervation and osteophyte resection or denervation and osteophyte resection of the patella during TKA. This will be done so that the results are comparable: In case of patellar resurfacing one resects the surrounding tissues of the patella in order to resect the patella. One also resects possible osteophytes. The patients will be randomly assigned to one of the two regiments in a 1:1 ratio. Investigators and patients will remain blinded to the assigned regiment.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients undergoing TKA in Martini hospital Groningen who show clinical and radiological signs of tricompartimental OA.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Rheumatoid arthritis;

2. Patella fracture;

3. Patella ligament transposition;

4. HTO;

5. Hip arthroplasty;

6. Other causes for anterior knee pain, i.e. PCL laesion;

7. Inability to read or write the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2011
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-10-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35479
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2961
NTR-old	NTR3108
CCMO	NL37901.099.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35479

Resultaten

Samenvatting resultaten
N/A