

PATRES: Una patella particolare.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25294

Source

Nationaal Trial Register

Brief title

PATRES

Health condition

Patellar resurfacing, patellaprothese, knieschijfvervanging

Sponsors and support

Primary sponsor: Martini Hospital, Department of Orthopaedic Surgery

Source(s) of monetary or material Support: Martini Hospital, Department of Orthopaedic Surgery

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary outcomes of the study are to:

1. Evaluate the Knee Injury and Osteoarthritis Outcome score (KOOS);
2. Evaluate the correlation between the Knee Injury and Osteoarthritis Outcome score (KOOS) and the patellofemoral scoring system by Baldini with regard to patellofemoral symptoms;
3. Evaluate the correlation between the Knee Society clinical rating system (KSS) and the patellofemoral scoring system by Baldini with regard to patellofemoral symptoms.

Study description

Background summary

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 arthroplasty.

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2011
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion	
Date:	18-10-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35479
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Register

OMON

ID

NL-OMON35479

Study results

Summary results

N/A