UNA PATELLA PARTICULARE Patellar resurfacing in total knee arthroplasty: a randomized controlled clinical trial

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Primary outcomeThe 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 24 months) compared to patients undergoing TKA without...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON35479

Source
ToetsingOnline

Brief title
PATRES

Condition

- Bone and joint injuries
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
patellar resurfacing

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: baldini scoring system, patella resurfacing, total knee artroplasty

Outcome measures

Primary outcome

During follow up, X-rays of the knee and physical examinations, including length, weight and leg axis, will be performed and questionnaires will be taken on several timepoints. X-rays of the knee will include Merchant and Baldini views as well as weight bearing axial views.

X-rays will be evaluated for component loosening, wear and patellofemoral problems including fracture or loosening of resurfaced patella, subluxation and wear of non-resurfaced patella.

Data (time) management and statistical analysis

Follow up X-rays Documentation

Day 0 Knee AP and Lateral Basic characteristics (incl. BMI)

Baldini and Merchant Questionnaire (KSS/ Baldini/KOOS)

Physical examination and weight

Informed consent

Randomisation

Operation Standardised report

Day 1- Day 5 Knee AP and lateral Wound check, function, KSS/Baldini/KOOS,

function at discharge

Week 6 Baldini and Merchant Wound check, KSS/Baldini/KOOS, function

Month 6 Questionnaire (KSS/ Baldini/KOOS)

Physical examination

Month 12 Knee AP and lateral Questionnaire (KSS/ Baldini/KOOS)

Baldini and Merchant Physical examination

Month 18 Knee AP and lateral Questionnaire (KSS/ Baldini/KOOS)

Baldini and Merchant Physical examination

Month 24 Knee AP and lateral Questionnaire (KSS/ Baldini/KOOS)

Baldini and Merchant Physical examination

Secondary outcome

Knee function: -study questionnaires

Questionnaires will include the Knee Society clinical rating system, the

patellofemoral scoring system by Baldini and the KOOS scoring system.

Questionnaires will be taken on several timepoints (table) by an independent

examiner.

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 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.

Study objective

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 24 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 outcomes
The secondary outcomes of the study are to:
-Evaluate the Knee Injury and Osteoarthritis Outcome score (KOOS)
-Evaluate the correlation between the Knee Injury and Osteoarthritis Outcome score (KOOS) and the patellofemoral scoring system by Baldini with regard to patellofemoral symptoms
-Evaluate the correlation between the Knee Society clinical rating system (KSS) and the patellofemoral scoring system by Baldini with regard to patellofemoral symptoms

Study design

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.

Intervention

Surgery:
The surgeon will start surgery according to the designated treatment allocation. He or she will start bij placing a total knee prosthesis. Then denervation of the patella and osteophyte resection.
- In the group of patients who have been randomised to receive patellarresurfacing the patella wil be resected and a hole will be drilled so that a patellabutton can be cemented into place
-Both groups will undergo the same procedure with the same incision and material so the only difference between the groups will be the patellarresurfacing

Study burden and risks

Risks accompanying the placement of a total knee replacement are similar for both treatment groups. Regarding the patellarresurfacing there is a risk of complications such aforementioned patellafracture, patellatendonrupture, soft tissue impingement, maltracking of the patella and patella-clunck syndrome.

Outpatient inspections take place after 6 weeks and then at 6, 12, 18 and 24 months after surgery. This means that these patients take three more outpatient visits than patients not participating in the study and have received a total knee prosthesis. Also completing the questionnaires which will take approximately 15 minutes extra to complete.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

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

Exclusion criteria

Patients with OA of the knee without patellofemoral OA
rheumatoid arthritis
patella fracture
patella ligament transposition
HTO
hip arthroplasty
Other causes for anterior knee pain, i.e. PCL laesion
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
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2011
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25294
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37901.099.11
OMON	NL-OMON25294