The ATtune Knee Outcome Study: prospective evaluation of a novel uncemented rotating platform knee system

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON55973

Source
ToetsingOnline

Brief title
ATKOS

Condition

- Joint disorders

Synonym
Knee Osteoarthritis; Knee cartilage wear-and-tear

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Gasthuis

Source(s) of monetary or material Support: DePuy Synthes,Johnson & Johnson

Intervention

Keyword: Implant design, Survival, Total Knee Arthroplasty, Uncemented

Outcome measures

Primary outcome

Survival rate and complication rate associated with the ATTUNE knee system.

Secondary outcome

- Patient Reported Outcome Measures (PROMS), which are the 'Forgotten Joint Score 12' and the 'Kujala Anterior Knee Pain Scale' for the current study.

- Physical function and return to sports, which is measured with 'Performance Based Measurments' (PBM) and 2 1-question questionnaires (Tegner and UCLA activity rating scale)

- Return to work is assessed by a short self-composed questionnaire, which evaluates what kind of work the patients do, when they started after surgery and whether this is the same as their preoperative job.

- A long-leg radiograph is performed 1 year after surgery to assess mechanical alignment of the prosthesis with consideration of femur and tibia.

- Psychologic factors are assessed with 3 questionnaires preoperative, 5 years and 10 years postoperative (Pain Self Efficacy Questionnaire (PSEQ); Patient Health Questionnaire (PHQ-2); Pain Catastrophizing Scale (PCS))

Study description

Background summary

Every year, 1.5 million total knee arthroplasties (TKA) are performed worldwide in patients whose joints have been severely affected by osteoarthritis, rheumatoid arthritis, or trauma, causing intense pain and loss of function. Due to the ageing society, these numbers are expected to have increased six-fold to 3.48 million cases annually by 2030. Even though joint replacement provides satisfactory and durable results for most patients, 20% is thought to still not be satisfied with their artificial joint. Preoperative mental status and related pain coping have been identified as factors that may lead to dissatisfaction. A review by Baert et al identified catastrophic thinking and poor coping capabilities to predict more pain after TKA, whereas evidence on the impact on knee function remains conflicting in nature. Most studies assess this influence only 1 year after surgery, with only the study by Brander et al prolonging the follow-up to 5 years. Brander et al found depression to still be associated with outcomes 5 years after TKA and reported significant improvements after the 1 year follow-up mark in the dissatisfied population. Whether pain catastrophising remains a significant predictor of dissatisfaction at long-term follow-up remains to be elucidated.
To accommodate this dissatisfied population and improve durability of implants even more, several knee systems have been developed over the years. One of the newest models is the ATTUNE knee system (DePuy, Warsaw, Indiana, USA), first implanted in 2011 and widely available since 2013. One of the landmark features is a gradually reducing radius in the geometry of the femoral component, more closely mimicking the anatomical patellofemoral joint and facilitating more natural femoral rollback during flexion. Comparisons of the cemented ATTUNE with previous knee systems show promising results in terms of patellofemoral outcomes, but fail to demonstrate definitive superiority in terms of all patient reported outcomes. Clinical superiority of the ATTUNE tends to abate with longer follow-up, implicating a possible superiority in the short-term recovery and return to activities. There is no follow-up study reporting the results of the uncemented ATTUNE. Moreover, all previously cited studies report better patellofemoral outcomes with patellar resurfacing, making it still unclear whether the implicated superior design changes of the femoral component hold ground without patellar resurfacing.
It is of utmost importance to assess the metric properties of a questionnaires when investigating an outcome. A recent study
showed the University of California Los Angeles (UCLA) activity scale to be the best measure for assessment of activity outcome
after arthroplasty surgery. To our knowledge, no validated Dutch version of the UCLA activity scale has been made.

Study objective

The primary objective is to report survivorship, complications and patient reported outcome measures associated with the uncemented ATTUNE rotating platform knee system. Secondary objectives are (1) evaluate patient reported (patellofemoral) outcomes (2) assess return to work and sport after TKA and (3) analyse psychologic factors (such as pain catastrophising and coping) and the

impact on dissatisfaction following TKA.

Study design

Multi-center prospective cohort study.

Intervention

The only difference with standard care is uncemented fixation of the prosthesis. Patients normally receive a cemented prosthesis in our institution (Spaarne Gasthuis), in other participating institutions uncemented fixation can be standard of care.

Study burden and risks

Overall, we believe the additional risks involved with the current study are minimal and limited to the extra radiation dosage for long-leg radiography, which is standard of care in many other institutions. The implant has been shown to migrate well below threshold after 2 years using RSA (which is a predictor for long-term fixation). Additional questionnaires and follow-up visits might be an inconvenience for some patients, but pose no extra risk and some patients may even like the extra attention and care given.

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

End-stage osteoarthritis of the knee warranting joint replacement therapy.

Capability and willingness to sign informed consent and comply with follow-up procedures.

Age between 21-90 years.

Capable enough in Dutch or English to be able to understand study procedures

Exclusion criteria

An a-priori risk for a posterior-stabilized knee system (history of patellectomy or preoperative flexion limitation <90 degrees)

Unable or unwilling to sign informed consent and comply with follow-up

Indication for primary revision arthroplasty

Absolute indication for cemented fixation (decreased bone stock/quality of spongiosa)

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-02-2020
Enrollment:	900
Type:	Actual

Medical products/devices used

Generic name:	Uncemented Attune Rotating Platform total knee arthroplasty
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-01-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 28720
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL71274.029.19