The ATtune Knee Outcome Study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28720

Source
Nationaal Trial Register

Brief title
ATKOS

Health condition

Knee Osteoarthritis

Sponsors and support

Primary sponsor: Spaarne Gasthuis
Source(s) of monetary or material Support: Spaarne Gasthuis

Intervention

Outcome measures

Primary outcome

Survivorship: Calculated by determining revision rate. Septic, aseptic and all-cause revision rates will be calculated seperately.

Complication rate: All substantial complications associated with total knee arthroplasty will be registered and reported

Forgotten Joint Score 12 (FJS-12)

Kujala Anterior Knee Pain Scale (AKPS)

Knee injury and Osteoarthritis Outcome Scale - Physical Function Short Form

KOOS-PS

Numeric Rating Scale (NRS): NRS on pain and satisfaction

EuroQol 5 Dimensions, 3 Levels (EQ5D-3L)

Secondary outcome

30 second chair stand test (30sCST): The amount of times one can stand up and sit down from a chair in 30 seconds

40m Fast paced walk test (40m-FPWT): The amount of seconds one does to walk 40 meters.

Stair climb test (SCT): The time one takes to walk a set of stairs up and down.

Tegner activity rating scale: 1-item questionnaire

University of California, Los Angeles (UCLA) activity rating scale: 1-item questionnaire

Return to work: 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

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

Patient Health Questionnaire (PHQ-2): 2-item questionnaire to screen for major depressive episodes

Pain Self Efficacy Questionnaire (PSEQ): Questionnaire to asses pain self efficacy

Pain Catastrophizing Scale (PCS): Explores pain catastrophizing and its relation to pain behaviour

Study description

Background summary

To accomodate dissatisfied patients with a total knee arthroplasty (TKA) and improve outcomes, several knee systems have been developed. The cemented ATTUNE TKA shows superiority over other established knee systems at short-term, abating with longer follow-up. There have been no studies reporting on the results of the uncemented version of the

ATTUNE. Therefore, the main objective of the current study was to report patient reported outcome measures (PROMs), survivorship and complications associated with the uncemented ATTUNE TKA.

Study objective

Compared with other well-established knee designs, the uncemented rotating platform ATTUNE knee system has similar outcomes regarding survivorship and complications, but may have improved early recovery.

Study design

1 year, 5 years and 10 years

Intervention

Total knee arthroplasty (TKA) with the uncemented ATTUNE rotating platform.

Contacts

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Eligibility criteria

Inclusion criteria

End-stage osteoarthritis of the knee warranting joint replacement therapy.
Indicated for an ATTUNE total knee system as part of regular clinical practice.
Capability and willingness to sign informed consent and comply with follow-up procedures.
Capable enough in Dutch or English to be able to understand study procedures

Exclusion criteria

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:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	28-09-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55973
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8929
CCMO	NL71274.029.19
OMON	NL-OMON55973

Study results