Long-term results of the AGC total knee arthroplasty system - 15 to 20 years survival and functional analysis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON31358

Source
ToetsingOnline

Brief title
Long-term results of the AGC total knee arthroplasty system

Condition

- Bone and joint therapeutic procedures

Synonym
arthrosis, wear of the joint

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Stichting Ortho Research Noord

Intervention

Keyword: AGC, functional analysis, survival, total knee arthroplasty

Outcome measures

Primary outcome

The main study parameter is the total number of failures in the cohort. Failure is defined as revision of one or more parts of the implant.

Secondary outcome

Secondary study parameters are function of the knee, physical functioning and quality of life of the patient and signs of loosening and wear. Other study parameters are age, gender, length and weight (body mass index), diagnosis, treated site, surgeon, comorbidity and complications.

Study description

Background summary

Total knee arthroplasty (TKA) is a well-established procedure, which generally results in relief of pain, improved physical function, and a high level of patient satisfaction. The Anatomic Graduated Component (AGC) TKA system is a common used implant in the treatment of osteoarthrosis and rheumatoid arthritis. To date, research is performed into the survival and functional outcome in studies with up to 15 years of follow-up.
The Orthopaedic department of the Martini Hospital Groningen, the Netherlands, began to use the AGC system in 1987. The cohort 1987-1992 will provide data on the 15 to 20 years survival of the AGC total knee arthroplasty system. This is an interesting cohort, because its follow-up term exceeds the 15 years follow-up described earlier in literature. Moreover, to the best of our knowledge, no survival and functional analysis of the AGC is performed in the Dutch population.

Study objective

Main objective is to determine the survival rate of the AGC total knee arthroplasty system with a follow-up of 15 to 20 years. Secondary Objective(s):

to determine the physical function of the patients by means of a physical examination and a questionnaire and to determine whether there are signs of loosening or wear of the prosthesis as shown on the X-ray. Additional objective is to perform research on the determinants of survival rate of the AGC total knee arthroplasty system.

Study design

The study is a retrospective cohort study. The cohort will consist of patients who had an AGC total knee arthroplasty between 1987 and 1992. The study will be executed at the Orthopedic department of the Martini Hospital in Groningen, the Netherlands. Duration of the study will be 6 months.

Study burden and risks

The burden for the participants is minimal. Only one visit to the outpatient clinic with a duration of 60 minutes is needed. The risks are negligible as a routine control procedure is followed.

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

AGC total knee arthroplasty system between 1987 and 1992

Exclusion criteria

AGC total knee arthroplasty system after 1992

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-09-2007
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	28-08-2007
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL18242.056.07