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Is there a difference in clinical outcome, pain, and range of motion between fixed and mobile bearing Attune total knee replacement?

Submission date
25/03/2022

Recruitment status
No longer recruiting

Registration date
04/04/2022

Overall study status
Completed

Last Edited
01/11/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Despite numerous scientific investigations, the tribological advantages of mobile bearing inserts have not been sustainably confirmed or refuted for modern knee prostheses in clinical studies. Simultaneously, total knee prostheses have substantially improved, especially in terms of the quality of polyethylene and fixation methods. Recent long term randomized controlled trials with large cohorts and literature reviews reported of no differences in durability, function, range of movement and migration. Modern total knee prostheses, such as the presented implant type (Attune®) provide a transition from stability and rotational freedom. This is the first study to analyze subjective and objective measurements between FB and MB inserts of this well-established TKA system.

Who can participate?
Every patient with end stage osteoarthritis that visited the outpatient department for Knee surgery at the Medical University of Graz between December 2015 and December 2016 was able to participate in this present study.

What does the study involve?
The study involves a surgical treatment (Total Knee Arthroplasty) and follow-up examinations over a 2-year follow-up period.

What are the possible benefits and risks of participating?
There were no specific or clinically relevant risks of participating as only as two well established Total Knee Arthroplasty systems were used in this present study.

Where is the study run from?
Medical University of Graz (Austria)

When is the study starting and how long is it expected to run for?
March 2018 to February 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Dr. med. Patrick Sadoghi, patrick.sadoghi@medunigraz.at

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
30-352 ex 17/18

Study information

Scientific Title
No difference in clinical outcome, pain, and range of motion between fixed and mobile bearing Attune total knee arthroplasty. A prospective single-center trial.

Study objectives
The purpose of this study was to compare fixed and mobile bearing inserts in order to draw conclusions regarding clinical benefits.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/03/2018, Ethics committee of the Medical University of Graz (Auenbruggerplatz 2, 8036 Graz, Austria; +43 316 385 13928; ethikkommission@medunigraz.at), ref: 30-352 ex 17/18

Study design
Prospective single center cohort study of 2 non-randomized stratified groups

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Comparison between fixed and mobile bearing inserts for Total Knee Arthroplasty in order to draw conclusions regarding clinical benefits

Interventions
All patients either received a fixed or mobile bearing insert during Total Knee Arthroplasty. The decision whether a patient received a mobile or fixed insert was made prior to the surgery based in a non-randomized setting. During the operation, the selection of insert type was not changed in any case.
Participants were followed up for a minimum of 2 years.

Between January 2015 and December 2016, a total of 544 primary total knee arthroplasties were implanted at one single orthopedic center. During this period another prospective level II study was conducted selecting patients of this time interval (n=200). The remaining 344 patients were eligible for the presented study. All patients either received a fixed or mobile bearing insert. The decision whether a patient received a MB of FB insert was made prior to the surgery based in a non-randomized setting. During the operation the selection of insert type was not changed in any case. Patients with a secondary arthritis, previous knee surgeries except arthroscopies, and varus/valgus-deformities of more than 20° were excluded. Moreover, we only included patients treated with one well-proved and worldwide used type of implant (Attune®, DePuy-Synthes, Warsaw, Indiana). All implants were tibial and femoral fixed with cement.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cemented total knee arthroplasty (Attune®) treated with a mobile or a fixed insert.

Primary outcome measure
Measured at for a minimum of 2 years follow-up.
1. Subjective assessment of success using the WOMAC score
2. Subjective assessment of success using Visual Analogue Scale
3. Range of Motion using the Knee-Society-Score

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
22/03/2018

Completion date
04/02/2020

Eligibility

Key inclusion criteria
1. End staged-osteoarthritis of the Knee Joint
2. Patients between 50-80 years of age
3. Signed consent to participate in the present study

Participant type(s)
All

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
85

Key exclusion criteria
1. Secondary Arthritis
2. Varus/Valgus deformities of more than 20°
3. Previous knee surgery except arthroscopy

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Austria

Study participating centre
Medical University Graz
Auenbruggerplatz 5
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Sponsor information

Organisation
Medical University of Graz

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Sponsor type
University/education

Website
http://www.medunigraz.at/en/

ROR
https://ror.org/02n0bts35

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/03/2022

Individual participant data (IPD) sharing plan
Available on request
patrick.sadoghi@medunigraz.at

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			04/04/2022	No	No
Results article		02/05/2022	22/09/2022	Yes	No