Multi-Center Clinical Evaluation of the ATTUNE® Revision System in Complex Primary Total Knee Arthroplasty

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Primary Objective There are two co-primary objectives; one regarding each tibial component configuration, fixed bearing (FB) and rotating platform (RP): 1) Evaluate change from preoperative baseline to the 2 yr timepoint in patient reported…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON54830

Source
ToetsingOnline

Brief title
DSJ-2016-03: Attune Complex

Condition

- Bone disorders (excl congenital and fractures)

Synonym
primary knee arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Medical Device Services, Inc.
Source(s) of monetary or material Support: Medical Device Business Services Ine. (formerly known as DePuy Synthes Joint Reconstruction a division

Intervention

Keyword: Arthroplasty, Complex, Knee, Post market

Outcome measures

Primary outcome

Primary Objective

There are two co-primary objectives; one regarding each tibial component configuration, fixed bearing (FB) and rotating platform (RP):

1) Evaluate change from preoperative baseline to the 2 yr timepoint in patient reported functional outcome, KOOS-ADL for the ATTUNE® Revision TKA FB configuration.

2) Evaluate change from preoperative baseline to the 2 yr timepoint in patient reported functional outcome, KOOS-ADL for the ATTUNE® Revision TKA RP configuration.

Secondary outcome

The secondary objectives of this study are:

* Evaluate change from preoperative baseline to the 5 yr timepoint in functional outcomes as measured using KOOS patient reported outcomes measure (PROM).

• Evaluate change from preoperative baseline to the 5 yr timepoint in functional outcomes and quality of life assessments, as measured using patient reported outcomes measures (PROMS) : PKIP (overall and sub-scores), AKS 2011 (Subject evaluations) and EQ-5D-5L.

• Evaluate change from preoperative baseline to the 5 yr timepoint in patient reported pain severity as measured using a modified VAS Pain Score (discrete

numbers rather than a continual scale).

• Evaluate change from preoperative baseline to the 5 yr timepoint in patient reported satisfaction over time as measured using a Likert scale.

• Estimate the change from preoperative baseline to the 5 yr timepoint in clinical outcomes using the 2011 AKS (surgeon evaluation)

• Evaluate type and frequency of Adverse Events

• Evaluate the timing, duration and reason for any readmissions stratified by adverse event type (operative site vs. systemic).

• Evaluate annual survivorship of the ATTUNE® Revision in complex primary TKA system for the FB and RP configurations and the combined FB and RP configurations using Kaplan-Meier survival analysis at 1, 2, 3, 4 and 5 years.

• Evaluate component*s fixation in complex primary TKA through zonal radiographic analysis of the femoral, tibial and patellar bone-implant interface at 1, 2 and 5 years after surgery compared to the first postoperative radiographs.

• Evaluate any changes in anatomic tibiofemoral, femoral component, tibial component and patellar component alignment at 1, 2 and 5 years compared to the first postoperative radiographs.

• Radiographically evaluate the restoration of joint line using the first postoperative radiographs according to the methodology of Figgie8

Study description

Background summary

The ATTUNE Revision system is new and without pre-existing clinical data. It is therefore important to conduct a post-market study to evaluate the short/medium term clinical performance and medium term survivorship of the implant system, which includes instrumentation, in complex primary TKA. In particular, this study will provide opportunities for active post-market surveillance of adverse effects in relation to use of the study device as well as providing both the patient*s and clinician*s perspectives of implant performance. Furthermore, an independent analysis of the study radiographs will provide unbiased and consistent data across the entire study population. Overall the study will result in a comprehensive dataset that will form the baseline for this implant*s medium term performance in the included population.

Study objective

Primary Objective
There are two co-primary objectives; one regarding each tibial component configuration, fixed bearing (FB) and rotating platform (RP):
1) Evaluate change from preoperative baseline to the 2 yr timepoint in patient reported functional outcome, KOOS-ADL for the ATTUNE® Revision TKA FB configuration.
2) Evaluate change from preoperative baseline to the 2 yr timepoint in patient reported functional outcome, KOOS-ADL for the ATTUNE® Revision TKA RP configuration.

Study design

This study is designed as a prospective, multi-center, non-randomized, non-comparative, non-controlled study. Level of evidence: III.

Study burden and risks

Subjects would be having a TKA regardless of their participation in the study and !here are risks associated with surgery (which are detailed in the protocol) but these risks are not specific tor participation in this study.
- Pre and post operatively follow up visits. The patient needs to complete some patient reported outcome instruments (Questionnaire).
- Xray AP and lateral and skyline will be taken at pre operatively, 6 Weeks, 1 year, 2 year and 5 year.

Contacts

Public
Medical Device Services, Inc.

Orthopaedic Drive 700
Warsaw 46581-0988
US
Scientific
Medical Device Services, Inc.

Orthopaedic Drive 700
Warsaw 46581-0988
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

a) Subject is male or female and between the ages of 22 and 80 years at the time of consent, inclusive.
b) The decision to have knee replacement with the study device is regardless of the research.
c) The devices are to be used according to the approved indications.
d) Subject that is willing to give voluntary, written informed consent to participate in this clinical investigation and authorize the transfer of his/her information to the Sponsor.
e) Subject is currently not bedridden.
f) Subject, in the opinion of the Investigator, is able to understand this clinical investigation and is willing and able to perform all study procedures and follow-up visits and co-operate with investigational procedures.
g) Subject is able to read, and comprehend the Informed Consent Document as well as complete the required PROMs in either
English or one of the available translations.
h) Subject has not been diagnosed with an inflammatory arthritis (including gout, rheumatoid, psoriatic etc.)

Exclusion criteria

a) The Subject is a woman who is pregnant or lactating.
b) Contralateral knee has already been enrolled in this study.
c) Subject had a contralateral amputation.
d) Previous partial knee replacement (unicompartmental, bicompartmental or patellofemoral joint replacement) or primary TKA in affected knee.
e) Subject is currently diagnosed with radicular pain from the spine that radiates into the limb to receive TKA.
f) Subject has participated in a clinical investigation with an investigational product (drug or device) in the last three (3) months.
g) Subject is currently involved in any personal injury litigation, medical-legal or worker*s compensation claims.
h) Subject, in the opinion of the Investigator, is a drug or alcohol abuser (in the last 5 years) or has a psychological disorder that could affect his/her ability to complete patient reported questionnaires or be compliant with follow-up requirements.
i) Subject was diagnosed and is taking prescription medications to treat a muscular disorder that limits mobility due to severe stiffness and pain such as fibromyalgia or polymyalgia.
j) Subject has a significant neurological or musculoskeletal disorder(s) or disease that may adversely affect gait or weight bearing activities (e.g., muscular dystrophy, multiple sclerosis, Charcot disease).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-10-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	ATTUNE Revision Knee System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-11-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-05-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT03153449
CCMO	NL62595.068.17