Multi-Center Evaluation of Post-Operative Recovery in ATTUNE Primary, Cemented Total Knee Arthroplasty

Published: 08-12-2014
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The primary objective of this study is to determine the rate of recovery of the ATTUNE knee from the time of surgery at the 6 month endpoint.

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

Summary

ID

NL-OMON44724

Source
ToetsingOnline

Brief title
ATTUNE NL

Condition

- Bone and joint injuries
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Osteoarthritis - Non-inflammatory Joint Disease

Research involving
Human

Sponsors and support

Primary sponsor: DePuy Synthes Joint Reconstruction, Inc.
Source(s) of monetary or material Support: DePuy Synthes Joint Reconstruction;Inc.

Intervention

Keyword: Osteoarthritis, Patient Reported Outcomes (PROs), Recovery, Total Knee Arthroplasty

Outcome measures

Primary outcome

The primary endpoint in this study is the KOOS-PS change from baseline to 6 months post-operatively, as estimated from a repeated measurements longitudinal model over all post-operative time points.

Secondary outcome

- KOOS-PS change from baseline at 6 weeks, 3 months, 1 year and 2 years, estimated from a repeated measurements longitudinal model.

- Days from surgery until discharge from the hospital.

- Kaplan-Meier Survivorship at 1 year and 2 years post-operatively, where revision is defined as the revision of any TKA component for any reason.

- The type and frequency of serious, device-related and/or procedure-related adverse events.

- All EQ-5D-5L dimensions will be estimated with unadjusted summary statistics at 3 months, 6, months, 1 year and 2 years post-operatively; summary statistics for changes from baseline will also be provided.

- New American Knee Society Scores (physician reported section) will be estimated with unadjusted summary statistics at 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively; summary statistics for changes from baseline will also be provided.

- Patient reported pain severity (with the index TKA) and change from baseline

at 3 months, 6 months, 1 and 2 years post-op.

- Patient reported satisfaction (with the index TKA) at 3 months, 6 months, 1

and 2 years post-op.

- Evaluation of the bone-implant interface at 1 year and 2 years

post-operatively using the recommendations of the American Knee Society

- Kaplan-Meier Survivorship at 1 year and 2 years post-operatively, where

revision is defined as the removal of any component for any reason with the

exception of infection.

- Trends in operating room time (surgical skin to skin time) will be analyzed.

Study description

Background summary

The ongoing DePuy Synthes Joint Reconstruction initiated clinical studies focus on patient reported outcomes at the 1 year time point and later and do not include multiple follow-ups during the recovery phase post-operative; hence, they will not be able to provide additional evidence to evaluate the early recocery. The primary objective of this study is to characterize the recovery phase after TKA with the ATTUNE knee in order to close this evidence gap.

Study objective

The primary objective of this study is to determine the rate of recovery of the ATTUNE knee from the time of surgery at the 6 month endpoint.

Study design

Prospective, multi-center, non-randomized, non-comparative, non-controlled study

Study burden and risks

- Preoperatively and at 5 postoperative follow-up visits (6 weeks, 3 months, 6 months, 1 year, and 2 years) the patient needs to complete patient-reported outcome instruments (Questionnaire, i.e. KOOS-PS, PKIP, EQ-5D-5L (not at 6

weeks) and Subject Knee Outcomes (not at 6 weeks).
- Preoperatively and at 3 postoperative follow-up visits (at 6 weeks or 3 months, 1 year, and 2 years) AP and lateral x-rays are taken.
- There is a risk for loss of privacy. Patients' private and confidential medical information may get disclosed and confidentiality broken.

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

a) Subject is male or female and between the ages of 22 and 80 years at the time of surgery, inclusive.
b) Subject was diagnosed with NIDJD resulting from osteoarthritis (OA) or post-traumatic arthritis.
c) Subject is a suitable candidate for cemented primary TKA using the devices described in

this CIP with either resurfaced or non-resurfaced patellae.
d) Subject has given voluntary, written informed consent to participate in this clinical investigation and has authorized the transfer of his/her information to DePuy Synthes Joint Reconstruction (see Section 6.3.2).
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 procedure and follow-up visits and co-operate with investigational procedures.
g) Subject is able to speak, read, and comprehend the Informed Consent Document as well as complete the PROs in the CIP in either Dutch or English translations.

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, bicompartamental or patellofemoral joint replacement), patellectomy, high tibial osteotomy or primary TKA in affected knee.
e) Subject is currently experiencing 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 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 their 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 (e.g. muscular dystrophy, multiple sclerosis, Charcot disease).
k) Subject is suffering from inflammatory arthritis (e.g. rheumatoid arthritis, juvenile rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus, etc.).
l) Subject has a medical condition with less than 3 years of life expectancy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2015
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	08-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-10-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT02339610
CCMO	NL49712.091.14

Study results

Date completed:	18-10-2018
Actual enrolment:	208