# Risk Factors for Aseptic Loosening after Primary Total Knee Arthroplasty with Cemented Knee Implants (Aseptic Loosening - Total Knee Arthroplasty)

**First published:** 03/09/2019
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Study    Ongoing

## Administrative details

**PURI**
https://redirect.ema.europa.eu/resource/31757

**EU PAS number**
EUPAS31269

**Study ID**
31757

**DARWIN EU® study**
No

**Study countries**
United States

**Study description**
Aseptic loosening (AL) is a major cause of failure of total knee arthroplasty (TKA), accounting for up to 31% of all failures. A systematic review conducted by Cherian et al evaluated risk factors for AL following both TKA and total hip arthroplasty (THA) procedures. Although there were conflicting results across studies, some investigations reported that patient-related factors such as smoking and BMI were associated with AL. This study was designed to evaluate risk of AL and revision due to AL in patients with cemented TKA. A retrospective longitudinal cohort study is described herein, using data

from claims and electronic health records from the US.Analyses include: Crude and adjusted cumulative incidence of AL and revision due to AL per post-index year. Survival analyses (Kaplan-Meier and weighted Cox models). Poisson regressions.Random-effect and fixed-effect models for aggregation of data from multiple databases, using DerSimonian & Laird (D.-L.) and Hartung-Knapp-Sidik-Jonkman (HKSJ) method.

**Study status**
Ongoing

# Research institution and networks

# Institutions

### Johnson & Johnson
**First published:** 01/02/2024
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**Institution**

# Contact details

**Study institution contact**
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**Study contact**

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**Primary lead investigator**
Jennifer Wood

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**
Planned:
03/09/2019
Actual:
09/09/2019

**Study start date**
Planned:

03/09/2019
Actual:
09/09/2019

**Data analysis start date**
Planned:
21/09/2019
Actual:
21/09/2019

**Date of interim report, if expected**
Planned:
01/11/2019

**Date of final study report**
Planned:
31/12/2019

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Johnson & Johnson

# Study protocol

RWE19_DEP_015 - Aseptic Loosening.pdf(357.35 KB)

# Regulatory

**Was the study required by a regulatory body?**
No

**Is the study required by a Risk Management Plan (RMP)?**
Not applicable

# Methodological aspects

# Study type

## Study type list

**Study type:**
Non-interventional study

**Scope of the study:**
Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**
Primary Objective: Evaluate the risk of: (1) Aseptic loosening and (2) revision due to aseptic loosening in patients following primary total knee arthroplasty with cemented implants.Secondary Objective: Evaluate patient, implant, procedure and provider related risk factors associated with aseptic loosening and revision due to aseptic loosening.

# Study Design

**Non-interventional study design**
Cohort

# Study drug and medical condition

**Medical condition to be studied**
Device loosening

# Population studied

**Age groups**
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

**Estimated number of subjects**
10000

# Study design details

**Outcomes**
Diagnosis of aseptic loosening.Revision with primary diagnosis of aseptic loosening.

**Data analysis plan**
Frequencies, proportions, means and standard deviations (SD) will be calculated to describe each database study population, and separately for patients with and without aseptic loosening (AL) diagnosis and AL revision procedures. Risk of AL and AL revision will be estimated at the following post-operative time points: 6 months, 1 year, 1.5 years, and yearly from 2 years onwards. A Kaplan-Meier analysis will be performed to evaluate risk of AL and AL revision over time, for the entire patient cohort. Poisson regressions will be used to model the incidence rates of AL and AL revision. A weighted Cox Regression analysis will be performed. Pooled estimates from results from the multiple data sources will be calculated using fixed and random-effect models, using DerSimonian & Laird (D.-L.) and Hartung-Knapp-Sidik-Jonkman (HKSJ) methods.

# Data management

# Data sources

**Data sources (types)**
Administrative data (e.g. claims)
Electronic healthcare records (EHR)

# Use of a Common Data Model (CDM)

**CDM mapping**
No

# Data quality specifications

**Check conformance**
Unknown

**Check completeness**
Unknown

**Check stability**
Unknown

**Check logical consistency**
Unknown

# Data characterisation

**Data characterisation conducted**
No