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

First published: 03/09/2019

Last updated: 09/10/2019

Study Ongoing

Administrative details

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 institutions and networks

Institutions

Johnson & Johnson

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Institution

Contact details

Study institution 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

10.000

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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Administrative healthcare records (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