Incidence and risk of heart failure in patients following metal-on-metal (MoM) hip arthroplasty

First published: 09/09/2019

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Study Ongoing

Administrative details

EU PAS number

EUPAS31333

Study ID

31754

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

Johnson & Johnson

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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: 11/07/2019

Actual: 11/07/2019

Study start date

Planned: 09/09/2019

Actual: 09/09/2019

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_SAF_004 Protocol_Final.pdf (295.54 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:

To estimate the incidence and evaluate the risk of heart failure among patients undergoing MoM arthroplasties of the hip compared with those with alternative types of arthroplasties (non-MoM)To estimate the incidence and evaluate the risk of heart failure among patients undergoing MoM arthroplasties of the hip compared with an age and gender similar Osteoarthritis cohort without arthroplasty

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Cardiac failure congestive

Population studied

Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

18.000

Study design details

Outcomes

Heart failure cases diagnosed in the first 30-days post implantation (index date) will be excluded to prevent including cases of iatrogenic fluid overload due to the surgical procedure>= 2 recorded acute heart failure-related diagnosis codes, Heart failure cases diagnosed in the first 30-days post implantation (index date) will be excluded to prevent including cases of iatrogenic fluid overload due to the surgical procedure>= 2 recorded acute or chronic heart failure-related diagnosis codes

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Data analysis plan

The goals of these analyses are to: 1) determine the characteristics of patients implanted with MoM and non-MOM hip implants and OA patients with arthroplasty, and 2) evaluate the risk of heart failure among patients with MoM implants compared to non-MOM implants or OA without arthroplasty.

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)

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