

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

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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

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Jennifer Wood [jwood61@its.jnj.com](mailto:jwood61@its.jnj.com)

Study contact

[jwood61@its.jnj.com](mailto:jwood61@its.jnj.com)

### Primary lead investigator

Jennifer Wood

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 11/07/2019

Actual: 11/07/2019

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### Study start date

Planned: 09/09/2019

Actual: 09/09/2019

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### **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

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

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## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**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)

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### **Estimated number of subjects**

18000

## 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  $\geq 2$  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  $\geq 2$  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

### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No