

# A cross-sectional study to evaluate the effectiveness of additional Risk Minimisation Measures: A Survey among surgeons to assess their knowledge and understanding of selected risks of InductOs (diboterminal alfa/ACS) in Europe

**First published:** 24/12/2019

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Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/42240>

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### EU PAS number

EUPAS32916

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### Study ID

42240

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## **DARWIN EU® study**

No

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### **Study countries**

- ☐ France
  - ☐ Germany
  - ☐ Ireland
  - ☐ United Kingdom
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### **Study description**

A cross-sectional study to evaluate the effectiveness of additional Risk Minimisation Measures for InductOs, more specifically of the educational materials that are distributed. This will be done through a survey among surgeons to assess their knowledge and understanding of the risk of occurrence of heterotopic ossification, and the related measures to minimize the occurrence of these risks.

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### **Study status**

Finalised

## **Contact details**

### **Study institution contact**

Koen Van der Heijden

**Study contact**

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### **Primary lead investigator**

Koen Van der Heijden

## Study timelines

### Date when funding contract was signed

Actual: 27/11/2019

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### Study start date

Planned: 21/09/2020

Actual: 01/10/2020

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### Date of final study report

Planned: 31/12/2020

Actual: 10/03/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Medtronic BioPharma B.V.

## Study protocol

[Protocol\\_PASS\\_InductOs\\_effectiveness aRMM.pdf](#)(387.93 KB)

## Regulatory

## Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### Study topic:

Human medicinal product

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#### Study type:

Non-interventional study

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#### Scope of the study:

Effectiveness study (incl. comparative)

#### Data collection methods:

Primary data collection

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#### Main study objective:

The goal of this study is to assess the awareness of InductOs-using spine surgeons concerning heterotopic ossification in relation to the InductOs Risk Management Plan.

## Study Design

## **Non-interventional study design**

Cross-sectional

## Study drug and medical condition

### **Name of medicine**

INDUCTOS

## Population studied

### **Short description of the study population**

Physicians from Germany, France, Ireland and the United Kingdom who have implanted InductOs in the last 2 years.

#### Inclusion criteria

Participants of this study must have met the following inclusion criteria to be eligible to participate in this study:

1. Physicians that have implanted InductOs in a lumbar interbody spine fusion procedure at least once in the 24 months prior to taking this survey

#### Exclusion criteria

Participants meeting any of the following criteria were not be included in the study:

1. Physicians that participated in the testing of this survey, if there are substantial changes made to the survey post-pilot i.e. changes which, in the view of the research team, make the participants contributions invalid or potentially compromising of the study objectives.
2. Physicians that either themselves work for or have immediate family

members who work for Medtronic, third parties involved in this study, or a regulatory agency (EMA, MHRA, HPRA, ANSM, BfARM).

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### **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

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### **Estimated number of subjects**

55

## Study design details

### **Data analysis plan**

The study population will include all physicians who are screened, are eligible for this study, and completed the questionnaire. All statistical summaries in this study will be descriptive. Frequencies and percentages, with 95 % confidence intervals (CIs) where appropriate, will be presented. Country specific data will be presented. Additional exploratory analyses and sensitivity analyses may be conducted to identify difference between groups of responders.

## Documents

### **Study results**

[Summary\\_PASS.pdf](#)(30.12 KB)

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## Data management

### Data sources

## Data sources (types)

Other

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## Data sources (types), other

Prospective data collection via a survey distributed to surgeons.

# 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