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 (dibotermin alfa/ACS) in Europe

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Study Finalised

Administrative details

EU PAS number

EUPAS32916

Study ID

42240

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] United Kingdom

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.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Koen Van der Heijden

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 27/11/2019

Study start date
Planned: 21/09/2020

Actual: 01/10/2020

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

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

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).

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

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)

Data management

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No