Effectiveness of Xiapex® educational material for healthcare professionals in the treatment of Dupuytren’s contracture - a non-interventional post-authorization safety study

First published: 26/06/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS19654

Study ID

40919

DARWIN EU® study

No

Study countries

Bulgaria

France

Romania

Slovenia

Study description

This study is to assess the effectiveness of the Xiapex educational material through a survey administered to physicians that have registering in the MAH’s Dupuytren’s Trained Physicians database and that are working in countries where Xiapex was launched after Dec -2016. Only those physicians who have been appropriately trained in the usage of Xiapex® in the treatment of Dupuytren’s contracture shall use Xiapex. The surveys will assess knowledge transfer of 5 domains (i.e., indication, injection procedure and posology, treatment cycles, extension, and the identified risks associated with Xiapex treatment). Overall, up to 20 physicians are expected to have received the survey within the distribution period of 01-Apr-2017 to 01-Apr-2020. The overall return rate is expected to be 80%. The primary endpoint will be summarized descriptively. Product withdrawn, study prematurely terminated.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maria Ilemosoglou

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2016

Actual: 01/06/2016

Study start date

Planned: 15/10/2017

Actual: 15/10/2017

Date of final study report

Planned: 01/04/2021

Actual: 31/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Swedish Orphan Biovitrum AB

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 type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The main objective of this study is to evaluate the effectiveness of the educational material in knowledge transfer of important safety information to the treating physician

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Physicians survey, Post-authorization safety study

Study drug and medical condition

Medicinal product name

XIAPEX

Medical condition to be studied

Dupuytren's contracture

Population studied

Short description of the study population

Physicians that have registering in the MAH’s Dupuytren’s Trained Physicians database and that are working in countries where Xiapex was launched after Dec -2016. Only those physicians who have been appropriately trained in the usage of Xiapex® in the treatment of Dupuytren’s contracture shall use Xiapex.

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

16

Study design details

Data analysis plan

The primary analysis set will consist of all physicians who have submitted the "Dupuytren’s contracture” survey.The primary endpoint, the correctness (yes, no) of answers to each of the 11 knowledge transfer questions, will be summarized descriptively.Missing data will be summarized descriptively.

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)

Other

Data sources (types), other

Physicians surveys

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