Effectiveness of Xiapex® educational material for healthcare professionals in the treatment of Peyronie’s disease - a non-interventional postauthorization safety study (201954)

First published: 27/01/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS11870

Study ID

42102

DARWIN EU® study

No

Study countries

Austria

Czechia

Denmark

Finland

Norway

Sweden

United Kingdom

Study description

With the cancellation of the Eperzan EU MA in January 2019, this post marketing study is no longer required or feasible to conduct. This is a non-interventional post-authorization safety study evaluating the effectiveness of the implemented additional risk minimization measure, i.e., the Xiapex educational material for healthcare professionals for treatment of Peyronie’s disease. The effectiveness will be assessed through a survey program which includes an Implementation survey and a Follow-up survey.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/01/2015

Actual: 30/01/2015

Study start date

Planned: 01/09/2016

Actual: 24/04/2015

Data analysis start date

Planned: 01/05/2017

Actual: 05/03/2018

Date of final study report

Planned: 31/12/2018

Actual: 10/01/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Swedish orphan Biovitrum AB

Study protocol

Study protocol_20Apr2015.pdf (500.83 KB)

Study protocol_Version 4_13 Apr2016 FINAL.pdf (1 MB)

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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The study objective is to evaluate the effectiveness of the Xiapex® educational material as an additional risk minimization measure for healthcare professionals in the treatment of Peyronie’s disease.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-authorization safety study, Survey

Study drug and medical condition

Medicinal product name

XIAPEX

Medical condition to be studied

Peyronie's disease

Population studied

Short description of the study population

Physicians registering in the MAH’s Peyronie’s Trained Physicians database who have received Xiapex educational material for healthcare professionals for treatment of Peyronie’s disease.

Upon registration in the Xiapex Peyronie’s Trained Physicians database the physician will consent to Sobi maintaining his/her information for the purpose of ensuring that only those physicians who are appropriately trained in the correct administration of the product and experienced in the diagnosis and treatment of male urological diseases can have access to Xiapex and for the purpose of assessing the effectiveness of the training programme. Physicians from Austria, Czech Republic, Denmark, Finland, Norway, Sweden, Spain and the United Kingdom registering in the Xiapex Peyronie’s Trained Physicians database will be asked to complete the survey. Distribution and return of surveys will be tracked.

Physicians that have not returned a completed form within 3 months following distribution will be asked to complete and return another survey for the purpose of soliciting information on nonresponding characteristics.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

30

Study design details

Data analysis plan

Categorical data from the Implementation survey and the Follow-up survey will be summarized using frequency counts and percentages using the categories defined in the survey. Adverse events identified will be coded using MedDRA. Number of responders and non-responders will be summarized in total and by country, and also by specialty.

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

Physician surveys assessing effectiveness of Xiapex education material.

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