Evaluation of the effectiveness of additional risk minimisation measures (aRMM) materials for Xeljanz® (tofacitinib) in Europe via a survey of healthcare professionals (HCPs): A non interventional (NI) post authorisation safety study (PASS)

First published: 29/09/2021

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47503

EU PAS number

EUPAS43143

Study ID

47503

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Netherlands
- [ ] Poland
- [ ] Romania
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

This is a cross sectional, non interventional, multimodal survey study that will be conducted among healthcare professionals who have prescribed Xeljanz for rheumatoid arthritis and/or psoriatic arthritis or ulcerative colitis in the 12 months preceding survey administration in 8 European countries (France, Germany, the Netherlands, Poland, Romania, Spain, Sweden, and the United Kingdom [UK]).

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea Leapley

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/06/2017

Actual: 27/06/2017

Study start date

Planned: 01/11/2021

Actual: 01/11/2021

Date of final study report

Planned: 18/04/2023

Actual: 14/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

A3921334 Evaluation of the effectiveness of addiitonal risk minimisation (aRMM) materials for Xeljanz (tofacitibib) in Europe via a survey of healthcare professionals (HCPs).pdf(6.34 MB)

A3921334_PROTOCOL- XELJANZ HCP SURVEY CLEAN_V3.0_28MAR2022.pdf(1.46 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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

the objectives of this study are to evaluate: • The aRMM program implementation ; • The HCPs’ knowledge of the key risk messages pertaining to special warnings and precautions associated with Xeljanz, as specified in the aRMM materials; and • The HCPs’ self reported adherence to the risk minimisation practices recommended in the aRMM materials.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Multimodal survey study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AA29) tofacitinib

tofacitinib

Population studied

Short description of the study population

The study population included healthcare professionals identified through the proprietary IQVIA OneKey database prescribed Xeljanz for the treatment of psoriatic arthritis (PsA), rheumatoid arthritis (RA), or ulcerative colitis (UC) in 8 European countries (France, Germany, the Netherlands, Poland, Romania, Spain, Sweden, and the United Kingdom).

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

300

Study design details

Outcomes

the number and proportion with -Awareness (Receipt) and Utilisation - Knowledge of Key Risk Messages -Adherence to the Risk Minimisation Practices

Recommended in the aRMM Materials, description of: -HCP Practice Characteristics; -Attitude Towards the aRMM Materials; -Source of HCPs' Information on the Safety of Xeljanz; -Response Rate, Cooperation Rate, Refusal Rate, and Contact Rate.

Data analysis plan

The data collected from the RA/PsA survey will be analysed separately from the data collected from the UC survey. For each survey (RA/PsA and UC), all primary analyses will be conducted using the pooled data from all countries, specialties (applies to the RA/PsA survey only), and indications (applies to the RA/PsA survey only), and will be descriptive in nature; no statistical comparisons within or between countries, specialties, and/or indications will be conducted. Only submitted and completed surveys i.e., all of Questions of the survey answered (taking into account skip patterns) by HCPs eligible to participate in the survey—will be used in the analyses. Categorical variables will be presented using frequencies and proportions. Continuous variables will be presented using means, standard deviations (SDs), minimums, 25th percentiles, medians, 75th percentiles, and maximums.

Documents

Study report

A3921334_FINAL STUDY REPORT_ 08DEC2022.pdf(1012.5 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

This study involves primary data collection. All data for analysis will be collected from HCPs directly via a multimodal survey instrument (i.e., a structured survey questionnaire implemented via Web portal or phone interview)

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