Post-Authorisation Active Safety Surveillance Program Among Patients Treated WithTofacitinib for Polyarticular Juvenile Idiopathic Arthritis (pJIA) and Juvenile Psoriatic Arthritis (PsA) Within the United Kingdom (UK) Juvenile Idiopathic Arthritis (JIA) Biologics Register

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/107204

EU PAS number
EUPAS107203

Study ID
107204

DARWIN EU® study
No

Study countries
United Kingdom

Study description
JIA is a heterogenous group of conditions, defined as arthritis persisting for 6 weeks or longer with no other identifiable cause and onset prior to age 16. JIA is the most common pediatric rheumatic illness, with an annual incidence in developed countries of 2 to 20 per

100,000 children and a prevalence of 16 to 150 per 100,000. Tofacitinib (Xeljanz®) is an oral Janus Kinase (JAK) inhibitor approved in the European Union(EU)in adult populations for the treatment of moderate to severe rheumatoid arthritis (RA), active PsA, and moderate to severe ulcerative colitis (UC). The important identified and potential risks associated with use of tofacitinib listed in the Risk Management Plan (RMP) include (but not limited to): venous thromboembolism, serious infections (including tuberculosis), herpes zoster or HZ, malignancy excluding NMSC, NMSC, lymphoma, lung cancer, interstitial lung disease, fractures, gastrointestinal perforations, all-cause mortality, PML, myocardial infarction (MI), and cardiovascular risk (excluding MI). Within the JIA population, additional events of interest include growth or development disturbances, and response to vaccination. Furthermore, drug hypersensitivity is considered as an identified risk and listed in the Summary of Product Characteristics (SmPC) but does not meet the criteria to be included in the RMP. As part of the tofacitinib pharmacovigilance plan, Pfizer will implement a post approval, active surveillance study of patients with pJIA or juvenile PsA initiating tofacitinib and those treated with approved bDMARDs using prospectively collected data included in the UK JIA Biologics Register to actively monitor the safety events of interest in the post-approval real-world setting, including events associated with long-term use.

Study status
Planned

Contact details

Study institution contact
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Study contact

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Primary lead investigator
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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
21/12/2021
Actual:
21/12/2021

Study start date
Planned:

01/10/2026

Date of interim report, if expected
Planned:
30/08/2026

Date of final study report
Planned:
01/05/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921409_PROTOCOL- TOFA JIA UK REGISTER_V1.0_ 03MAY2023.pdf(630.84 KB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 3 (required)

Other study registration identification numbers and links

A3921409

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Main study objective:
To estimate the post-approval incidence rate of the following outcomes of interest among patients with pJIA or juvenile PsA who initiate tofacitinib and patients with pJIA or juvenile PsA treated with approved bDMARDs: venous thromboembolism, serious infections and other important infections, all malignancies combined (excluding NMSC), lymphoma (examined separately), and lung cancer.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
Xeljanz

Population studied

Age groups
Children (2 to < 12 years)
Adolescents (12 to < 18 years)

Estimated number of subjects
1

Study design details

Data analysis plan
Crude incidence rates (IRs) of events overall and stratified by baseline characteristics such as disease activity, subtype of JIA, treatment type defined as monotherapy or combination therapy with MTX on the index date, and prior JIA therapy in both tofacitinib cohort and comparator cohort will be calculated. A comparative analysis will examine the risk of the outcomes of interest among patients from the tofacitinib cohort compared to the patients from the comparator cohort adjusting for confounding by baseline characteristics. Propensity scores will be estimated using baseline characteristics described in the study protocol. Propensity score adjusted IR (per 100 PY) and associated 95% CI will be calculated for the outcomes of interest, for which there are adequate data using an exact Poisson method. Where there are adequate data to compare the risk between cohorts,

multivariable Cox proportional hazards models will be fit to compare risk of the outcome of interest.

Data management

Data sources

Data sources (types)
Disease registry

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