An evaluation of non-melanoma skin cancer and melanoma skin cancer rates among patients treated for moderately to severely active rheumatoid arthritis with Xeljanz® (tofacitinib citrate): A retrospective non-interventional database study of observational data embedded within Optimising Patient outcome in Australian RheumatoLogy - Quality Use of Medicines Initiative (OPAL-QUMI) (Skin cancer rates in OpaL - SOL study)

First published: 03/04/2017

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS18431

Study ID

40879

DARWIN EU® study

No

Study countries

Australia

Study description

Xeljanz® (tofacitinib citrate) is a potent, selective inhibitor of the Janus kinase (JAK) family of kinases with a high degree of selectivity against other kinases in the human genome. It was approved for use in Australia Feb 2015 and PBS listed (reimbursement) in Oct 2015. Being the first oral JAK inhibitor for the treatment of moderate to severe RA, there is a need to gather emerging real-world long-term safety data. These data will help to further contextualise and expand knowledge about the benefit:risk profile of Xeljanz in RA. To permit assessment of NMSC and MSC rates among RA patients being treated with Xeljanz in the post-approval setting, Pfizer will support a database study utilising data collected within the Optimising Patient outcome in Australian RheumatoLogy (OPAL) network, a clinician driven point of care observational data management consortium. The OPAL network is made up of Australian private-practice rheumatologists who agree to share a clinical record system for data gathering. Several studies have already been published based on data collected from this combined cohort. This protocol outlines operational and analytical aspects of a database study within the OPAL network to describe rates of NMSC and MSC among patients with RA treated with Xeljanz, stratified by patient demographics and clinical characteristics. The analyses will be based on enrolled incident users of Xeljanz for RA treatment. Similar data will also be collected for patients treated with biologic disease-modifying anti-rheumatic

drugs (bDMARDs) to provide context about rates and types of NMSC/MSC in real-world Australian clinical practice. This study does not aim to perform formal comparisons between Xeljanz and bDMARDs.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Networks

OPAL-QUMI

Contact details

Study institution contact

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Primary lead investigator

Edith Owens

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/04/2016

Actual: 20/04/2016

Study start date

Planned: 19/05/2017

Actual: 09/05/2017

Data analysis start date

Planned: 19/05/2017

Actual: 09/05/2017

Date of final study report

Planned: 30/05/2022

Actual: 10/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921291 NIS Protocol.pdf (657.78 KB)

A3921291_PROTOCOL_Amendment 1.pdf (175.98 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

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

Data collection methods:

Secondary use of data

Main study objective:

To determine rates of NMSC and MSC among Australian patients with moderately to severely active RA treated with tofacitinib or biologic disease modifying anti-rheumatic drugs. Data will be stratified by patient demographics and clinical characteristics.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Medicinal product name

XELJANZ

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

Patients aged 18 years or older diagnosed with rheumatoid arthritis (RA), received treatment with tofacitinib or a bDMARD and have at least 1 year of follow-up, identified from the OPAL registry, extracted for the period of 01 February 2015 until 01 September 2018.

Exclusion criteria:
Patients with any autoimmune rheumatic disease or inflammatory bowel conditions except for RA (eg, psoriatic arthritis, ankylosing spondylitis, psoriasis Crohn’s
disease or ulcerative colitis) are excluded.

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)

Special population of interest

Other

Special population of interest, other

Patients with rheumatoid arthritis

Estimated number of subjects

3000

Study design details

Outcomes

To determine the rate of Melanoma Skin Cancer and Non-Melanoma Skin Cancer among patients treated for moderately to severely active RA, as measured by DAS28 at baseline, with tofacitinib, To determine the rate of Melanoma Skin Cancer and Non-Melanoma Skin Cancer among patients treated for moderately to severely active RA, as measured by DAS28 at baseline, with biologic disease modifying anti-rheumatic drugs

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Data analysis plan

Patients meeting the inclusion and exclusion criteria described above will be categorised into one of two mutually exclusive drug cohorts, based on the type of DMARD received (tofacitinib or bDMARDs). All continuous variables will be summarised using n (non-missing sample size), mean, standard deviation, median, minimum and maximum. The frequency and percentages (based on the non-missing sample size) or observed levels will be reported for all categorical measures. Descriptive summaries will be produced for each data cut, providing there is sufficient data available, and again at the final analysis. All summaries are descriptive and there are no comparative analyses being undertaken, therefore, no adjustments for multiple data cuts and multiple endpoints are required. Patients who discontinue their index treatment (tofacitinib or bDMARD) will continue to be followed for a period of 1 year.

Documents

Study results

A3921291 Non Interventional Study Report Abstract_Redacted.pdf (325.1 KB)

Study report

A3921291 Non Interventional Study Report 12 October 2021_Redacted.pdf (3.66 MB)

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)

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