Canadian Non-Interventional Study of Xeljanz in Rheumatoid Arthritis (CANTORAL)

First published: 26/10/2017
Last updated: 22/02/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/49540

EU PAS number
EUPAS21413

Study ID
49540

DARWIN EU® study
No

Study countries
Canada

Study description
The study will describe the baseline, characteristics of Canadian RA patients initiating tofacitinib in clinical practice and subsequently assessing disease activity, patient reported outcomes, and persistence of response.

Study status
Finalised

Research institution and networks

Institutions

Pfizer
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Institution

Multiple centres: 50 centres are involved in the study, Adachi Medicine Professional Corp, Hamilton, Canada, Manna Research Inc, Burlington, Canada, Nexus Clinical Research, St John's, Canada, Clinical Research and Arthritis Centre, Windsor, Canada, Oshawa Clinic, Oshawa, Canada, Clinique Medicale Viau, Saint-Leonard, Canada

Networks

JSS Medical Research

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Edith Owens
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
01/07/2017
Actual:
12/07/2017

Study start date
Planned:
15/10/2017
Actual:
31/10/2017

Data analysis start date
Planned:
30/11/2019

Date of final study report
Planned:
30/05/2023
Actual:
09/05/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

A3921280_FINAL PROTOCOL V1.1_02OCT2017.pdf(378.03 KB)

A3921280 Protocol Amendment 4 19Jan2022.pdf(2.11 MB)

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:
Effectiveness study (incl. comparative)
Safety study (incl. comparative)

Data collection methods:
Primary data collection

Main study objective:
1) To describe the profile of RA patients initiating treatment with tofacitinib in the Canadian real – world/clinical setting. 2) To describe the clinical effectiveness of tofacitinib over time in patients with moderate to severe RA in the real-world/clinical setting.

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
Observational, multi-centre study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(L04AA29) tofacitinib

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) treated with tofacitinib.
Inclusion Criteria:
1. Adult patients, at least 18 years of age or older at the time of recruitment.
2. Diagnosis with RA as per the revised 1987 American College of Rheumatology (ACR) criteria or 2010 ACR/EULAR criteria.
3. Patients for whom the treating physician has made the decision to commence tofacitinib treatment in accordance with the Canadian Product Monograph.
4. Initiation of treatment with tofacitinib within 28 days from study enrolment.
5. Acceptance for patients to participate in the study and the signing of the informed consent.

Exclusion Criteria:
1. Patients who do not have the ability answer the questionnaires by themselves or who have any kind of disorder that may affect their answers.
2. Patients diagnosed with autoimmune rheumatic diseases other than RA.
3. Cannot or will not sign informed consent.
4. Active participation or enrollment in an interventional trial.
5. Previous experience with tofacitinib through either a clinical trial or previous treatment.
6. Is not expected to be available for follow up assessments as required for adequate management.
7. According to the judgment of the physician will not be able to participate in the study including the presence of any condition that, in the opinion of the treating physician, prohibits the patient from participating in the study or obscures the assessment of the treatment of RA.

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
500

Study design details

Outcomes
The primary outcome variable of the study will be the Clinical Disease Assessment Index (CDAI). Tender Joint Count, Swollen Joint Count, DAS28, SDAI, Physician Global Assessment of Disease Activity, Patient Global Assessment of Disease Activity, Patient Subjective Assessment of Pain, Health Assessment Questionnaire Disability Index, Routine Assessment of Patient Index Data-3, EuroQol, Work Productivity and Activity Impairment: Treatment Satisfaction, Fatigue, Health Resource Utilization

Data analysis plan
The analyses conducted for the study will be predominantly descriptive with several associations assessed with bivariate and multivariate methods. However, given that there are no specific a-priori defined hypotheses being tested, there is no need for multiplicity correction for the number of associations tested and the number of outcomes assessed. Hence any p-values presented should be considered as descriptive statistics themselves, and, there will be no declarations of statistical significance. The analyses will be conducted on observed cases without imputation for missing data in order to preserve the observational nature of the study. The Full Analysis Set (FAS) will be comprised of all enrolled patients providing consent to participate in the study. Nevertheless, the use of mixed effects models will help to compensate for missing observations, patient attrition and unequal time intervals between assessments.

Documents

Study results
A3921280 Non Interventional Study Report Abstract 01 May 2023_Redacted.pdf(1.91 MB)

Study report
A3921280 Non Interventional Study Report 01 May 2023_Redacted (2).pdf(5.86 MB)

Study, other information
A3921280_NON-INTERVENTIONAL STUDY ABSTRACT v4.0_19Jan2022.pdf(1.76 MB)

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Prospective patient-based data collection

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