A Descriptive Retrospective Database Study to Evaluate Serious Clinical Manifestations and Outcomes among SARS-CoV-2 Diagnosed Patients with RA, PsA or UC treated with systemic therapies: A Post Approval Safety Study of Tofacitinib in the Context of the COVID-19 Pandemic

First published: 29/05/2020

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS35384

Study ID

42208

DARWIN EU® study

No

Study countries

United States

Study description

The research questions addressed by this study are: • What proportions of SARS-CoV-2 diagnosed patients have a diagnosis of RA, PsA, or UC (ie, indicated subcohorts) or not (i.e. non-indicated subcohort) and what is risk of serious clinical manifestations and outcomes of interest in these subcohorts? • Within the indicated subcohorts of SARS-CoV-2 diagnosed patients, what is the proportion treated at baseline with the following systemic therapies: tofacitinib, JAK inhibitors, TNFi, non TNFi, and csDMARD and what is risk of serious clinical manifestations and outcomes of interest within strata? This is a retrospective cohort study involving secondary analysis of Optum administrative databases in the US consisting of longitudinal health information about patients tested for or diagnosed with SARS-CoV-2. The data source will be periodically updated and evaluated throughout the course of the study period. The dataset consists of longitudinal data for patients from a subset of healthcare systems that expedite reporting of SARS CoV 2 diagnoses, tests and their results. This dataset has been selected in the study in order to identify early insights into the potential risks of SARS CoV 2 for indicated patients overall and by therapy. This study is an active surveillance study consisting of repeat analyses over multiple time points, beginning with a 30 April 2020 data cut and repeated quarterly (summarized per quarter as well as cumulatively) in order to understand the SARS CoV 2 infected patients over time and across geographies as the virus spreads.

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

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/05/2020

Actual: 01/05/2020

Study start date

Planned: 18/05/2020

Actual: 23/05/2020

Date of final study report
Planned: 11/10/2023

Actual: 11/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921380_PROTOCOL and APPROVAL_COVID PASS_15May2020 .pdf (2.4 MB)

A3921380_Protocol Amendment 2 Version 3.0 (clean)_COVID PASS_28 August 2023_Redacted.pdf (3.6 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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

What proportions of SARS-CoV-2 diagnosed patients have RA, PsA, or UC or not and what is risk of serious clinical manifestations & outcomes of interest in these subcohorts? What is the proportion treated at baseline with the following systemic therapies: tofacitinib, JAK inhibitors, TNFi, non TNFi, and csDMARD & what is risk of serious clinical manifestations and outcomes by treatment strata?

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AA29) tofacitinib

tofacitinib

Medical condition to be studied

Rheumatoid arthritis

Colitis ulcerative

Psoriatic arthropathy

Population studied

Short description of the study population

The study population involved patients aged 18 years or older diagnosed with SARS-CoV2 identified from the Optum covid testing database.
Inclusion criteria:
1. SARS-CoV2 diagnosis
2. At least 6 months of continuous enrollment prior to index date
3. Age 18 or older at index date

For indicated subcohort: Evidence of RA, PsA, UC diagnosis withing baseline period prior to index date.
For non-indicated subcohort: No evidence of RA, PsA, UC diagnosis withing baseline period prior to index date.

Exclusion criteria:
1. There are no exclusion criteria for this study.

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

Immunocompromised

Other

Special population of interest, other

Patients with SARS-CoV2 infection

Estimated number of subjects

1.385.530

Study design details

Outcomes

Determine the proportions of patients with a diagnosis of RA, PsA, & UC, describe baseline demographic characteristics, treatment history and comorbidities, estimate proportion experiencing serious clinical manifestations and outcomes of interest, determine the proportions of patients treated with the following systemic therapies at baseline: tofacitinib, JAK inhibitors, TNFi, non-TNFi & csDMARD.

Data analysis plan

After selection of the study population, summary statistics of baseline variables will be determined for the baseline period. The index date for each patient is defined as the first date that the study inclusion criteria are satisfied. Baseline

variables will be summarized as appropriate for categorical and continuous variables with 95% CI provided to show precision of the estimate. Among patients who are included in the study, outcomes will be included that occur during the risk window from index date until the first of death (based on discharge status), 3 months post SARS CoV 2 diagnosis, or end of study period/datacut. The endpoints of interest within each indication, non indicated subcohort and indication/treatment combination will be summarized as appropriate for categorical and continuous variables with 95% CI provided to show precision of the estimate.

Documents

Study results

A3921380 Non Interventional Study Report Abstract 21 June 2023_Redacted.pdf (1.27 MB)

Study, other information

A3921380 Non Interventional Study Report 11 September 2023_Pages 51-97 Redacted.pdf (5.34 MB)

A3921380 Non-Interventional Protocol Abstract 12 May 2020.pdf (1.75 MB)

A3921380_Protocol Amendment 1 (clean)_COVID PASS_20 July 2021.pdf (2.37 MB)

Data management

Data sources

Data source(s), other

Optum covid testing database

Data sources (types)

Administrative healthcare records (e.g., claims)

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