Comparative safety of abatacept in rheumatoid arthritis with COPD: A real-world population-based observational study

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Study Ongoing

Administrative details

EU PAS number

EUPAS25405

Study ID

25561

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

Centre d'Épidémiologie Clinique de Montreal

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Teresa Simon

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 19/10/2016

Study start date

Actual: 01/01/2007

Date of final study report
Planned: 31/10/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To assess whether treatment with abatacept for RA among patients with COPD is associated with an increased risk of COPD exacerbation, bronchitis and pneumonia/influenza compared with other BDMs.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Infective exacerbation of chronic obstructive airways disease

Pneumococcal infection

Influenza

Bronchitis

Population studied

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

12.650

Study design details

Outcomes

Primary outcomes of interest include COPD exacerbations, bronchitis and pneumonia/influenza, Secondary outcome will be combining COPD exacerbation, bronchitis and pneumonia/influenza

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Data analysis plan

Descriptive statistics will be calculated within each database to compare baseline characteristics between patients who are prescribed abatacept and other BDMs. The primary analysis will be based on the cox proportional hazards regression model to estimate the hazard ratio and 95% CI of each outcome event comparing patients using abatacept with users of other BDMs, further adjusted for confounders found to be unbalanced despite matching on propensity scores.

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)

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