Post-marketing Study Assessing the Long-term Safety of Abatacept

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Study Finalised

Administrative details

EU PAS number

EUPAS8718

Study ID

18489

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a retrospective cohort study that will be conducted using administrative health care databases in the United States to estimate and compare the risk of malignancies and infections among patients exposed to abatacept and patients

exposed to other treatments for rheumatoid arthritis (RA).

Study status

Finalised

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicole Baker

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 08/10/2013

Study start date
Planned: 01/06/2014

Actual: 01/06/2014

Date of final study report
Planned: 31/12/2016

Actual: 27/01/2017

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 topic:

Disease /health condition

Human medicinal product

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 estimate and compare the risk of malignancies and infections among a cohort of RA patients whoare prescribed abatacept and a cohort of patients who are prescribed other RA treatments.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

ABATACEPT

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

Patients with risk of malignancies and infections among a cohort of rheumatoid arthritis (RA) patients who are prescribed abatacept and a cohort of patients who were prescribed other RA treatments.

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

Rheumatoid arthritis patients

Estimated number of subjects

140000

Study design details

Outcomes

Primary outcomes of interest include lung cancer, lymphoma, breast cancer, non-melanoma skin cancer, all malignancies, hospitalized infections, pneumonia, opportunistic infections and tuberculosis. lupus, multiple sclerosis and psoriasis

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Data analysis plan

Descriptive analyses of the data will be conducted. Overall incidence rates and rates stratified by age group and sex will be calculated. Unadjusted and adjusted Cox proportional hazards regression analyses will be performed.

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 source(s), other

Ingenix (OptumInsight) United States, Truven MarketScan Commercial United States, Truven marketScan Supplemental Medicare United States, IMS LifeLink: PharMetrics Plus - US

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

Unknown