An Analysis of Real-World Data on the Safety of Etanercept in Elderly Patients with Rheumatoid Arthritis

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Study Finalised

Administrative details

EU PAS number

EUPAS25655

Study ID

25656

DARWIN EU® study

No

Study countries

United States

Study description

Both rheumatoid arthritis (RA) and older age are associated with a higher risk of comorbidities, and the appropriate treatment approach for older patients is unclear. We evaluated real-world data (RWD) to determine whether there is an association between etanercept (ETN) and select adverse events (AEs) in patients with RA, stratified by age. We hypothesized that there is no difference in risk of AEs between younger (aged ≤65 yr) and older (aged >65 yr) patients.

Study status

Finalised

Research institutions and networks

Institutions

Truven MarketScan

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Heather Jones

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/09/2012

Study start date
Actual: 26/03/2018

Date of final study report
Actual: 05/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

EUPAS25655_protocol.pdf (221.42 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 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:

Both RA and older age are associated with a higher risk of comorbidities, and the appropriate treatment approach for older patients is unclear. We evaluated RWD to determine whether there is an association between ETN and select AEs in patients with RA, stratified by age. We hypothesized that there is no difference in risk of AEs between younger (aged ≤65 yr) and older (aged >65 yr) patients.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ENBREL

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

Elderly Patients with Rheumatoid Arthritis.

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

450.000

Study design details

Outcomes

The primary outcome is that we determine that our hypothesis is correct that there is no difference in risk of certain AEs between younger (aged ≤65 yr) and older (aged >65 yr) patients using Enbrel. Determine the risk of CHF, SI, NMSC, and ILD in patients using Enbrel

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Data analysis plan

Data from 2013 to 2018 were analyzed from the IBM Watson Health MarketScan Database which contains information on 104.5 million distinct patients, including 531,996 with RA. Patients were required to be enrolled ≥1 yr prior to RA diagnosis, the first exposure to ETN was after RA diagnosis and before the AE of interest: congestive heart failure (CHF), serious infection (SI), non-melanoma skin cancer (NMSC), or interstitial lung disease (ILD). Proportion of patients experiencing each AE was determined for patients ≤65 yr and >65 yr receiving and not receiving ETN. Differences were evaluated using Fisher's Exact test. Logistic regression models assessed the interaction between ETN and age group. Propensity matching was performed, and logistic regression was applied using the propensity-score-matched cohort. Patients receiving and not receiving ETN were matched by age, age >65 yr, gender, and geographical region.

Documents

Study results

results.pdf (360.66 KB)

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

Unknown