Evaluation of the effectiveness of the abatacept (ORENCIA®) intravenous and subcutaneous formulation Patient Alert Cards in patients with rheumatoid arthritis in a sample of European Economic Area countries

First published: 30/06/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10122

Study ID

31062

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

The patient alert cards (PACs) for the use of intravenous (IV) and subcutaneous (SC)formulations of abatacept are to be evaluated as part of the post-marketing commitment to the European Medicines Agency (EMA) by Bristol-Myers Squibb (BMS). Three epidemiological sub-studies will be conducted: a patient survey of understanding and implementation of the key messages in the abataceptPACs, a health care professional (HCP) survey of understanding and implementation of the key messages in the abatacept PACs and a Clinical Outcomes Study using retrospective chart review to correlate clinical and safety outcomes with levels of understanding and implementation of the key messages in the PACs.

Study status

Finalised

Research institutions and networks

Institutions

OXON Epidemiology

- [ ] Spain
- [ ] United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

Multiple centres: 40 centres are involved in the study

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

Actual: 05/10/2014

Study start date
Actual: 15/10/2016

Date of final study report
Actual: 07/09/2017

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?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The main objective of the study is to evaluate the effectiveness of the abatacept PACs by:1. Assessment of the distribution, awareness, utilisation, utility, knowledge, comprehension and behaviour by patients and HCPs.2. Correlation of measures of the distribution, awareness, utilisation, utility, knowledge, comprehension and behaviour reported by patients in the same patients.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Healthcare professional survey, patient survey and retrospective chart review study

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 rheumatoid arthritis and rheumatologists/nurses.

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

Estimated number of subjects

400

Study design details

Outcomes

Patient survey: proportion of correct responses to individual questions about receipt, knowledge, understanding and acting on the advice contained in the abatacept PACs.HCP survey: proportion of correct responses to individual questions about understanding and mplementation of key messages contained in the abatacept PACs.Outcomes evaluation: proportion of infections leading to hospitalization. Patient survey:determinants of patient knowledge and understanding and implementation of the key messages.HCP survey:determinants of HCP understanding and implementation regarding key messages.Outcomes:mean time from infection to medical attention, proportion of: patients with results of tests to screen for tuberculosis/viral hepatits, emergency room visits, umplanned hospitalisation.

Data analysis plan

For the patient and HCP questionnaires, the percentage of patients/HCPs with responses to each question that indicate effectiveness of the PAC will be determined: receipt, awareness, usage, knowledge and comprehension of key messages. The primary endpoints of the patient survey responses indicating understanding and implementation will be analysed by baseline patient characteristics. The primary endpoints of the HCP survey responses indicating understanding and implementation of the PACs will be analysed by baseline HCP characteristics. Correlation between patients' degree of understanding and implementation of the messages in the PACs with infections leading to hospitalisation and with other secondary endpoints will be studied through regression techniques.

Documents

Study results

IM101537Orencia_FSR Abstract_v1.0_07Sep2017.pdf(74.44 KB)

Data management

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)

Other

Data sources (types), other

Web-based patient and healthcare professional surveys.Retrospective chart review study using an electronic case report form.

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