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: 01/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/31062

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 institution 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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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, k

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

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