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: 03/06/2026

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 abatacept patient alert PACs, 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 patient PACs.

Study status

Finalised

Research institutions and networks

Institutions

OXON Epidemiology

Spain

United Kingdom

First published: 06/12/2010

Last updated: 03/06/2026

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:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Cross-sectional surveys of HCPs and patients

A retrospective chart review

Main study objective:

The main objective of the study was to evaluate the effectiveness of the abatacept (ORENCIA®) IV and SC Patient Alert Cards (PACs) by: (1) assessing awareness, distribution, utilisation, utility, knowledge, comprehension and behaviour among patients and healthcare professionals (HCPs); and (2) evaluating the association between these measures in patients and the occurrence of infections leading to hospitalisation 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

Medicinal product name

ORENCIA

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

ABATACEPT

Anatomical Therapeutic Chemical (ATC) code

(L04AA24) abatacept

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

Setting

The study was conducted in France, Germany, Spain, Sweden and the United Kingdom. It comprised three epidemiological sub-studies: a patient cross-sectional survey, an HCP cross-sectional survey, and a retrospective chart review of patients treated with abatacept for rheumatoid arthritis. Eligible patients had received abatacept within the previous 3 months; eligible HCPs had prescribed, administered or managed abatacept-treated patients within the previous 6 months.

Outcomes

Patient survey: awareness, distribution, utilisation, utility, knowledge/comprehension, behaviour/communication implementation, and overall understanding and implementation of key PAC messages.

HCP survey: awareness, distribution, utilisation, utility,

knowledge/comprehension, behaviour/communication implementation, and overall understanding and implementation of key PAC messages.

Clinical outcomes study: proportion of patients with infections leading to hospitalisation (primary outcome); proportion screened for tuberculosis and viral hepatitis before abatacept initiation; time from infection symptom onset to receiving medical attention; infections leading to emergency room visits; and unplanned hospitalisations.

Data analysis plan

Descriptive analyses were performed to estimate awareness, distribution, utilisation, utility, knowledge/comprehension and behaviour outcomes among patients and HCPs. Associations between baseline characteristics and understanding/implementation of key messages were evaluated using univariate and multivariable logistic regression analyses. Correlations between patient understanding/implementation scores and clinical outcomes were assessed using regression techniques and Kaplan–Meier methods for time-to-event analyses.

Summary results

Among patients, 60% were aware of the PAC, 95% of those aware had received it and 84% had read it. Knowledge of infection risks was higher among patients who had received the PAC. Among HCPs, 90% were aware of the PAC and 68% had accessed it. The proportion of patients with infections leading to hospitalisation increased as understanding and implementation scores decreased, although the association was not statistically significant. Overall, the results supported the effectiveness of the abatacept PACs.

Documents

Study results

IM101537Orencia_FSR Abstract_v1.0_07Sep2017.pdf (74.44 KB)

Study publications

Artime, E., Kahlon, R., Méndez, I., Kou, T., Garrido-Estepa, M., & Qizilbash, N...

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)

Electronic healthcare records (EHR)

Other

Patient surveys

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