Patients’, physicians', nurses’ and pharmacists’ preferences toward the attributes of biological agents used in the treatment of rheumatic diseases in Italy (MK-0000-330) (CARA)

First published: 02/04/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6140

Study ID

47234

DARWIN EU® study

No

Study countries

☐ Italy

Study description

This study was conducted to determine patients', physicians, nurses' and pharmacists' preferences toward the attributes of biological agents used in the treatment of three rheumatic conditions: rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis, in Italy.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Institution **Pharmaceutical company**

Multiple centres: 34 centres are involved in the study

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC
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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/09/2013

Study start date
Planned: 30/06/2014

Actual: 16/06/2014

Data analysis start date
Planned: 31/07/2015

Actual: 31/07/2015

Date of final study report
Planned: 30/06/2016

Actual: 30/06/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The primary objective is to assess the most preferred attributes and the importance of biologics for the management of rheumatic diseases in a real setting according to the different treatment characteristics and points of view and experiences of the different categories of involved subjects (patients, physicians, nurses and pharmacists).

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Descriptive, observational, cross-sectional, open, multicenter, stated preferences study

Study drug and medical condition

Medical condition to be studied

Rheumatoid arthritis

Ankylosing spondylitis

Population studied

Short description of the study population

The study sample included 1) patients, 2) rheumatologists, 3) nurses and 4) pharmacists meeting the inclusion criteria and the characteristics necessary according to the objective of the study.

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

740

Study design details

Outcomes

1) To estimate the relative importance according to preferences assigned to the attributes of biological treatments and to explore differences and similarities between the different categories of participants: patients, physicians, nurses and pharmacists. 2) To identify socio-demographic, clinical and other characterisitics that may influence paitient preferences for treatment.

Data analysis plan

The statistical package STATA will be used to conduct the analysis. For all statistical tests, a p-value <0.05 will be considered statistically significant.

Missing data (e.g. dubious, ambiguous, inconsistent) on socio-demographic and clinical information will be properly identified (e.g. “99”) in the data base and specified in the final report of study results. Unclear data will be traced back, addressed with the participating rheumatologist, and contrasted with the patient’s health record (whenever possible). If data amendment is not possible, data will be regarded as missed.

Documents

Study results

CARA study - Summary CLINICAL STUDY REPORT Final version 30.06.16 signed.pdf(136.84 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)

Other

Data sources (types), other

Prospective patient-based data collection

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

No