Achieving Minimal Disease Activity and Predictors of clinical response in Patients with Psoriatic Arthritis treated with Golimumab in clinical practice: a Multicenter Observational Study (MK-8259-039)

First published: 03/02/2015

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Study Finalised

Administrative details

EU PAS number

EUPAS8426

Study ID

47237

DARWIN EU® study

No

Study countries

Italy

Study description

This study aims to develop a clinical prediction model for the achievement of 6-month minimal disease activity (MDA) in psoriatic arthritis (PsA) patients starting golimumab. PsA patients who have been newly prescribed golimumab in routine clinical practice will be invited to participate in the study. Data in this observational study will be collected from multiple clinics throughout Italy. Information from a clinical predictive model will permit clinicians to tailor treatments to individual patients and practice more effective and personalized medicine, optimizing the outcomes of patients with PsA.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Institution **Pharmaceutical company**

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Actual: 25/06/2014

Study start date

Planned: 20/04/2015

Actual: 23/04/2015

Data analysis start date

Planned: 29/11/2016

Actual: 29/11/2016

Date of final study report

Planned: 21/08/2017

Actual: 20/07/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharpe & 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:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

To develop a clinical prediction model, using a combination of baseline (pre-antiTNF treatment) clinical variables, for the achievement of 6-month MDA in PsA patients starting golimumab.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicenter, prospective, observational study

Study drug and medical condition

Medical condition to be studied

Psoriatic arthropathy

Population studied

Short description of the study population

The study population included all patients referred to participating clinics and diagnosed with Psoriatic arthritis (PsA) that fulfilled the study inclusion and exclusion criteria.

A subject had to meet all the criteria listed below to participate in the study.
1. Adult ≥ 18 years of age with PsA predominantly characterized by peripheral synovitis (as per CASPAR [Classification Criteria for Psoriatic Arthritis] criteria);
2. Subject non-responder or insufficient responder to the conventional therapies according to physician’s decision;
3. Subject newly prescribed golimumab as indicated by the treating physician according to usual clinical practice;
4. Patient was informed of the potential benefits and risks of golimumab as per normal practice using the patient alert card and the product leaflet
5. Concomitant treatment with traditional DMARDs was allowed according to investigators’ decision.
6. Naive to anti-TNFs or other biologic agents prior to initiation of golimumab as indicated by the patient’s medical records. In addition, this was evaluated by the investigator and patient interview during screening.
7. Data on the following parameters (a set of core variables) had to be available at enrolment (prior to the first injection of golimumab): age, gender, BMI, diagnosis duration (duration since date of diagnosis), information on presence/absence of polyarthritis, ESR/CRP, concurrent DMARD, functional disability measure (e.g. HAQ), disease activity measure (DAPSA). The associated timeframe for the acute phase reactants as well as clinical and functional outcome measures availability were ± 4 weeks of golimumab prescribed;
8. Signed informed consent form. The informed consent included a section relating to the request for consent for evaluation of biomarkers in serum from blood sample as per the Italian Ministry of Health regulation (AIFA Determination of March 2008).
9. Each female subject had to agree to use a medically accepted method of contraception while partic

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

140

Study design details

Outcomes

Response rate to treatment defined as proportion of patients achieving MDA at 6 months. 1. Proportion of patients achieving MDA at 3 months.2. Evaluation of clinical outcomes at 3 and 6 months (change vs. baseline)o Change in Leeds Enthesitis Indexo Change in dactilytis scoreo Changes in functional score (by Health Assessment Questionnaire)

Data analysis plan

For developing of the clinical prediction model of MDA a backward stepwise selection strategy will be applied to multivariable logistic model. Statistical interactions will be systematically fitted between statistically significant variables. The overall performance of the model will be evaluated by the Brier score. Discriminatory ability will be evaluating estimating the c-statistics, and calibration evaluated both statistically and graphically by the Hosmer-Lemeshow goodness-of-fit test and the calibration plot. Further logistic models

will be fitted including biomarker levels as additional candidate predictors. The improvement of the performance of the prediction models will be evaluated by estimating the integrated discrimination improvement (IDI) index.

Documents

Study results

MK 8259-039 p039mk8259_final-redaction_body.pdf (911.24 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