Juvenile arthritis Methotrexate/Biologics long-term Observation (JuMBO)

First published: 12/08/2014

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Study Ongoing

Administrative details

EU PAS number

EUPAS7196

Study ID

28986

DARWIN EU® study

No

Study countries

Germany

Study description

JuMBO is a prospective observational cohort study and represents the follow-up register of the national juvenile idiopathic arthritis (JIA) biologic register "BiKeR". It was set up to assess the safety and effectiveness of biologic and

non-biologic disease modifying antirheumatic drugs (DMARDs) in adult subjects with JIA under real life conditions in 2007.Subjects observed in JuMBO were formerly included in BiKeR, have reached 18 years of age or have left paediatric care, and were ever treated with a biologic and/or non-biologic DMARD. Each subject is followed prospectively for up to 10 years after starting with a specific DMARD. Patients are half-yearly assessed by a short clinical record and a patient questionnaire. The measuring instruments comprise among others the following parameters: number of swollen and/or tender joints, physician's overall assessment of disease activity, patient’s global assessment of overall well-being, laboratory values (CrP, ESR), functional status (Health Assessment Questionnaire), patient’s assessment of pain, morning stiffness, quality of life (SF-36, EuroQoL), hospitalizations, costs, mortality, time on biologic or MTX therapy, and reasons for change of treatment. Adverse events (AEs) and serious adverse events (SAEs) are recorded according to the EMA guidance “Clinical safety data management: definitions and standards for expedited reporting”, ICH Harmonized Tripartite Guideline. AEs occurring during the observation period are recorded by physicians regardless of the patients´ current treatment. In addition to physician-reported AEs, patients are asked to report health problems. Therewith, JuMBO enables the identification of important AEs and their associations with therapeutic agents. In addition, the data collected allow for describing treatment patterns of JIA in adulthood, examining long-term clinical and patient-centered outcomes, and costs of illness

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Study status

Ongoing

Research institutions and networks

Institutions

German Rheumatism Research Centre Berlin (Deutsches Rheuma-Forschungszentrum Berlin, DRFZ)

Germany

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Angela Zink

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/07/2007

Study start date
Actual: 01/04/2007

Data analysis start date
Actual: 01/07/2008

Date of interim report, if expected
Actual: 31/07/2010

Date of final study report
Planned: 31/12/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer GmbH, Abbvie GmbH & Co. KG, Gentech/Roche

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Cost of illness

Main study objective:

The aim of JuMBO is to describe the long-term safety, effectiveness, and cost of biologic drugs, especially of etanercept, adalimumab, and tocilizumab, in JIA in comparison to a conventional DMARD therapy (MTX). In order to achieve this goal, the patients already enrolled in BiKeR are to be observed after reaching adult age and/or leaving the pediatric rheumatology care.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AB01) etanercept

etanercept

(L04AB04) adalimumab

adalimumab

(L04AC07) tocilizumab

tocilizumab

(L04AX03) methotrexate

methotrexate

Medical condition to be studied

Juvenile idiopathic arthritis

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

Estimated number of subjects

2.000

Study design details

Outcomes

1. To study the long-term safety of nonbiologic (nb) DMARDs and biologic (b) DMARDS in young adults with JIA by recording the frequency, kind, severity and consequences of serious and non-serious adverse events.2. To evaluate the long-term effectiveness outcomes of nbDMARDs and bDMARDS by assessing disease activity, function, pain, final height, quality of life and duration under therapy. 1. To determine cost effectiveness of etanercept, adalimumab, and tocilizumab by analyzing direct and indirect costs as well as treatment

outcomes including quality of life.2. To provide DNA samples for a joint pharmacogenetic study with the study center Sankt Augustin and the University of Calgary aiming at the identification of genetic predictors influencing efficacy and toxicity of drugs.

Data analysis plan

The following statistical principles will be applied in JuMBO for safety and effectiveness analyses: (i) propensity score methods (confounding by indication), (ii) Cox regression (confounder adjustment, changing risks), (iii) Generalized regression models for survival data (confounder adjustment, changing risks, recurrent AEs), (iv) Generalized estimation equations (confounder adjustment, changing risks, recurrent AEs) and (v) Missing data models (missing data). In case patients are lost to follow-up, the reasons for study non-completion are determined and comparisons of drop-outs and non-drop outs are performed. Furthermore, survival analysis methods will be used to study treatment adherence of biologic drugs and the reasons for discontinuation. All subjects who received at least one dose of a specific biologic DMARD will be included in the safety analysis.

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, Exposure registry

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