Pharmacovigilance In Juvenile Idiopathic Arthritis Patients Treated With Biologic Agents And/Or Methotrexate. A Pediatric Rheumatology International Trials Organisation (PRINTO)/Pediatric Rheumatology European Society (PRES) Registry (Pharmachild JIA registry)

First published: 25/05/2011

Last updated: 15/05/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1974

Study ID

49777

DARWIN EU® study

No

Study countries

- [ ] Albania
- [ ] Argentina
- [ ] Australia
- [ ] Austria
- [ ] Belgium
- [ ] Bosnia and Herzegovina
- [ ] Brazil
- [ ] Bulgaria
- [ ] Chile
- [ ] China
- [ ] Colombia
- [ ] Costa Rica
- [ ] Croatia
- [ ] Denmark
- [ ] Egypt
- [ ] El Salvador
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Georgia
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] India
- [ ] Iraq
- [ ] Israel
- [ ] Italy
- [ ] Latvia
- [ ] Libyan Arab Jamahiriya

- [ ] Lithuania
- [ ] Mexico
- [ ] Montenegro
- [ ] Netherlands
- [ ] New Zealand
- [ ] Norway
- [ ] Oman
- [ ] Paraguay
- [ ] Peru
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Russian Federation
- [ ] Saudi Arabia
- [ ] Serbia
- [ ] Slovakia
- [ ] Slovenia
- [ ] South Africa
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] Türkiye
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] Venezuela, Bolivarian Republic of

Study description

Juvenile idiopathic arthritis (JIA) is the most common chronic paediatric rheumatic disease (PRD) and an important cause of short and long-term disability and quality of life impairment. Although none of the available drugs

for JIA has a curative potential, prognosis has greatly improved as a result of substantial progress in disease management. The therapeutic treatment of children with JIA encompasses the use of non-steroidal anti-inflammatory drugs (NSAIDs) and intra-articular steroid injections. In those patients not responding to NSAIDs, methotrexate (MTX) has become the disease modifying anti-rheumatic drug (DMARD) of first choice worldwide. For children not responding to MTX, biologic agents recently have become treatment options. This 3-10 year project will observe children with JIA undergoing treatment with MTX or biologic agents, as the primary disease model and has the following objectives: 1. To create a long-term observational registry of a large population of prevalent and incident cases of JIA treated with MTX with or without concurrent biologic agents. 2. Use the accumulating data in the registry to conduct (i) a pharmacovigilance/safety study (primary endpoint) and (ii) estimate effectiveness (frequency and magnitude of response, inhibition or slowing of joint erosions and other radiological evidence of disease progression), and (iii) estimate adherence to the various treatment regimens. Data from the registry will be used to compare safety and effectiveness profiles amongst the patient cohorts. 3. To identify clinical and laboratory predictors of safety, response to therapy, including remission The rationale underpinning this collaborative project is to combine the efforts of paediatric rheumatologists belonging to the PRINTO/PRES network in order to guarantee a critical mass of patients' data and to provide systematically obtained evidence for development of guidelines for health authorities.

Study status

Ongoing

Research institutions and networks

Institutions

IRCCS Istituto Giannina Gaslini, Pediatric Rheumatology International Trials Organisation (PRINTO)

☐ Italy

First published: 01/02/2024

Last updated: 01/02/2024

Institution **Not-for-profit**

Networks

Paediatric Rheumatology International Trials Organisation (PRINTO)

☐ Austria
☐ Belgium
☐ Bulgaria
☐ Croatia
☐ Cyprus
☐ Czechia
☐ Denmark
☐ Estonia
☐ Finland
☐ France
☐ Germany
☐ Greece

- [ ] Hungary
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- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

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Network ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicolino Ruperto

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/04/2011

Study start date

Planned: 01/02/2012

Actual: 19/12/2011

Data analysis start date

Planned: 01/09/2020

Date of final study report

Planned: 01/10/2025

Sources of funding

- EU institutional research programme

More details on funding

EU project number 260353

Study protocol

Pharmachild_protocol_v3.pdf(242.64 KB)

Pharmachild_protocol_v4.pdf(243.63 KB)

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

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

•To assess the long-term safety and efficacy of biologic agents and MTX for the treatment of children and adolescents with JIA. •To compare incidence rates of

emergent moderate, severe adverse events (AEs) and serious A (SAE) observed in paediatric subjects with JIA

Study Design

Non-interventional study design

Cohort

Cross-sectional

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Name of medicine

ILARIS

SIMPONI

Anatomical Therapeutic Chemical (ATC) code

(L04AA24) abatacept

abatacept

(L04AB01) etanercept

etanercept

(L04AB02) infliximab

infliximab

(L04AB04) adalimumab

adalimumab

(L04AB05) certolizumab pegol

certolizumab pegol

(L04AC03) anakinra

anakinra

(L04AC04) rilonacept

rilonacept

(L04AC07) tocilizumab

tocilizumab

Medical condition to be studied

Juvenile idiopathic arthritis

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

3000

Study design details

Outcomes

Proportion of JIA paediatric subjects with biologic agents and MTX -emergent moderate/severe and SAEs, referred as:•All moderate/severe AEs and SAEs,•All additional moderate/severe AEs and SAEs which may modify the safety profile

of biologic agents and MTX. •Three to 10-year and longer probability of not experiencing AEs•Incidence rate of biologic agents and MTX-emergent moderate/severe AEs and SAEs in a JIA population in comparison with incidence rates observed in JIA subjects treated with MTX in association with other DMARDs•Frequency of subjects meeting the ACR Pediatric criteria for improvement and clinical remission on and off medication

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Data analysis plan

Analysis will be mainly descriptive in nature. For continuous numeric data (e.g. baseline demographic data such as age), the descriptive statistics including number of subjects (n), mean, standard deviation (SD), median, and inter-quartile ranges will be summarized by dose group. For categorical data, the frequency count will be presented by dose group. Safety and tolerability will be summarized by treatment group. The number and percentage of subjects experiencing treatment emergent adverse event will be summarized by system organ class, preferred term, and treatment group. The number and percentage of subjects with clinically important laboratory abnormalities and vital signs measurements during the treatment period will be summarized by dose.Concomitant medications will be tabulated by generic drug name. Moderate/severe AEs and SAEs will be coded according to the current version of MedDRA.

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

EUPAS1974-1994.pdf(55.05 KB)

Composition of steering group and observers

Steering and Observer Comm.pdf(153.4 KB)

Signed code of conduct

2011-0005-CoCdecl 10.05.2011.pdf(48.31 KB)

Signed code of conduct checklist

2011-0005-CoCcklist 10.05.2011.pdf(888.29 KB)

Signed checklist for study protocols

2011-0005-Protocol Chlist 10.05.2011.pdf(182 KB)

Data sources

Data sources (types)

Disease registry

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