Lay Title: How do comorbidities burden patients with Juvenile Idiopathic Arthritis?

Author: Nico Wulffraat UMC Utrecht, Netherlands,
Collaborating partners: Utrecht (Wulffraat, Swart for Pharmachild), Manchester (Hyrich/Lunt for UK JIA Treatment Registers), Genoa (Ruperto for Pharmachild), Berlin/ Sankt Augustin (Minden/Klotsche and Horneff for JuMBO/Biker), ENCA (Wendy Costello, chair and Schoemaker for the Dutch JIA parent organisation).

1. Objective of the project

The purpose of this proposal is to study the presence of comorbidity and diseases developing under therapy of patients followed in the 3 largest JIA registries in Europe. We assume that comorbidity in a disease such as JIA significantly increases the burden of the disease and thus has major effects on the quality of life.

2. Background

Comorbidity can be defined as the presence of 2 disorders or more occurring at the same time in a single patient. Usually comorbidity accumulates with increasing age in the elderly. In addition, children with chronic diseases such as JIA can develop complications of the disease itself, a new disease or drug related side effects that have a significant impact on the quality of life. In this project we want to study all significant events occurring before or after the onset of arthritis. In children such events are mostly rare.

For the many new medications for JIA, long term follow up for safety and efficacy is important. Therefore large databases (also called registries) have been started. Such databases can in theory detect rare disease associations and complications, possibly related to the primary disease or its therapy.

3. Methods and approach

Our aim is to bring together data of at least 10,000 JIA patients from the 3 largest JIA registries in Europe (1 multinational registry Pharmachild, 1 from UK and 1 from Germany). In these registries, data are collected on disease activity, medication, quality of life and complications. From our general experience we expect to find disorders occurring before the onset of arthritis as well as major complications related to JIA such as uveitis (eye inflammation), side effects from therapy such as growth failure, but we will also look for newly developed inflammatory bowel disease, autoimmune diseases and even malignancies.

Detailed studies will be performed on the quality and comparability of the data, the correlation of comorbidities and JIA specific variables, and the impact on the quality of life. After an initial evaluation of baseline characteristics and events occurring in these patients, we will organize meetings with patient organisations to discuss the impact of such comorbidity on the lives of JIA patients and ask them to rank them for severity, in order to set our joint research agenda.

4. Primary and secondary outcome measures:

This project will provide detailed data on comorbidity and its burden on the JIA disease course in 3 large separate registries. This has not been studied before. It is of value to provide data on health care outcomes for JIA in the 3 separate registries. An important secondary outcome is that we will study in detail how the data are collected in the 3 registries and determine how they can be compared.

5. Recruitment of participants (if appropriate)

Anonymous data from patients that already consented to participate will be used. So this is re-use of already existing data for which patients gave their consent.

6. Inclusion and exclusion criteria (if appropriate)

The inclusion criteria of the registries are all JIA subtypes. There are no exclusion criteria.

7. Expected benefits for patients

Patients and parents must cope with a chronic disorder that has a variety of disabling effects, related to damage of the musculoskeletal system, pain, fatigue, and psychosocial effects. Development of comorbidity in addition to JIA increases the disease burden. Better understanding of the impact of JIA complications, adverse effects of drugs and comorbidity in general will enable early and targeted care.

8. Expected benefits for society

The aforementioned data can be used as quality indicators and are valuable across Europe for health care providers (the doctors in the hospitals), health care authorities and health care insurance companies.

9. Burden for patients participating in this study

Since this is re-use of already existing data there is no research related extra burden for patients.

10. Patient involvement:

These quality parameters are highly relevant for patient organisations since these must be addressed by local health care providers and authorities. We invited European Network for Children with Arthritis (ENCA) representatives in our steering committee. ENCA has parents trained in research, epidemiology and health care amongst its members.

The PRES council (from the Pediatric Rheumatology European Society) has supported the SHARE project (lead by Wulffraat) that focusses on these aspects in close collaboration with ENCA and several national parent/patient organisations. Patient involvement through ENCA can help us analysing the relevance of the comorbidity for the disease burden. They will be actively involved in ranking the importance of the observed comorbidities/complications and thus in discussing priorities for further research. Parents/patients can evaluate obtained information on these events via websites with patient information and hospital-websites.

Patient voice

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Meet the Team

The Netherlands

-Prof N Wulffraat, Pediatric rheumatologist Wilhelmina Children's Hospital / UMC Utrecht, PI of this study and PI of Pharmachild-registry

-Joost Swart, Pediatric rheumatologist UMC Utrecht NL, researcher of this study and Pharmachild-registry

UK

-Professor Kimme Hyrich, PI CAPS and 2 biologic registers in children with arthritis in the UK, Professor of Epidemiology and Consultant in Rheumatology, University of Manchester

-Dr. Mark Lunt, Reader in Medical Statistics, University of Manchester

-Lianne Kearsley-Fleet, Research Assistant , University of Manchester

Italy

-Dr. Nicolino Ruperto: Project Manager, Co-PI Pharmachild-registry, Senior Scientist of the Paediatric Rheumatology International Trials Organization (PRINTO, www.printo.it); located at Istituto Giannina Gaslini of Genoa

-Dr. Gabriella Giancane: Medical doctor researcher

-Dr. Chiara Pallotti: Research assistant

Germany

-Prof K Minden and Dr J Klotsche, PIs of JuMBO-register, German Rheumatism Research Centre and Charité University Medicine Berlin.

-Prof G Horneff, Sankt Augustin, PI BiKeR-register

Europe

-Mrs W Costello, Ireland, Chairman of the European Network for Children with Arthritis (ENCA)

-Dr. C Schoemaker, Representative of the Dutch JIA Parent Association