27th PRINTO newsletter | May 2018

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25th PReS Meeting 2018 in Lisbon

The 25th European Pediatric Rheumatology Congress (PReS 2018) will be held from 5th to 8th September 2018 in Lisbon, Portugal. The Congress will take place at the Lisbon Congress Center (CCL) which is located close to the river Tagus and the historical and cultural heritage of Belem, just a few minutes from the city center, in a prime area with a vast transport supply.

In line with previous congresses organized by PReS, this will be a place for challenging presentations and enriching debates of the more recent scientific investigations, including new syndromes and their treatment, trials for old diseases of young people and an up-to-date of care of the more severe juvenile rheumatic diseases.

In this occasion valuable abstracts will be presented both by young and mature Pediatric Rheumatologists from Europe and around the World and they will certainly help to advance the field of Pediatric Rheumatology both in basic science and in clinical practice.

For more info please go to http://www.pres.eu/pres2018/index.html

We are looking forward to seeing you in Lisbon!

2019 Meeting of the International Society of Systemic Autoinflammatory Diseases (ISSAID)

The 10th Biannual Meeting of the International Society of Systemic Autoinflammatory Diseases (ISSAID) will be held in Genoa on March 31st- April 3rd, 2019.

The main topics will be classical autoinflammatory diseases, mechanisms of disease, new diseases, immune dysregulation, HSCT and gene therapy, as well as dermatology as a special topic.

For more details please visit www.issaid2019.org
PRINTO ongoing projects

The PRINTO Evidence-based Revision of the International League Against Rheumatism (ILAR) Classification criteria for juvenile idiopathic Arthritis

“The PRINTO Evidence-based Revision of the International League Against Rheumatism (ILAR) Classification criteria for juvenile idiopathic Arthritis” is a new translational study with the objective of collecting data to validate the proposed new PRINTO Classification criteria for juvenile idiopathic Arthritis. This project is financed by the Italian Ministry of Health.

In December 2015, an international consensus conference has been convened by researchers of the IRCCS Giannina Gaslini (PRINTO headquarter) in order to reach a consensus on the new PRINTO JIA classification criteria. The 13 consensus panelists proposed the following distinct 6 PRINTO JIA categories: Systemic arthritis, RF positive arthritis, Enthesitis/spondylitis related JIA, Early onset ANA+, Other JIA, Unclassified JIA. With a data collection of at least 1,000 children at JIA onset, this project will provide a validation for the proposed classification.

The project includes the enrollment of a prospective cohort of at least 1,000 JIA patients, evaluated at onset and at 4 times points since the disease onset (within the first and after at least 3 months the second and then at least annually up to year 5). Related biologic samples will be collected at the first 2 time points (ANA, anti CCP, RF, HLA B27). The left over of the HLA B27 samples will be used for additional genetic analysis providing the family/patient consent/assent and additional approval by the ethics committee (if needed). This phase represents the core of the validation process. It will also include ultrasound evaluation (limited to few selected centres still to be identified) at each visit in order to examine the potential added value that might be provided to the new classification criteria by the use of imaging techniques.

All PRINTO centres have been invited to participate in this project with a dedicated survey a few days ago and the PRINTO coordinating centre will offer assistance during the Ethics Committees submission phase.

Comparison of STep-up and step-down therapeutic strategies in childhood ARthritiS (The STARS trial)

The STARS (comparison of STep-up and step-down therapeutic strategies in childhood ARthritiS) trial is a new interventional trial financed by AIFA (Agenzia Italiana del Farmaco) and by the Italian Foundation Compagnia di San Paolo that will be conducted by PRINTO only in the Italian centres. This clinical trial has the aim to investigate whether an early aggressive therapeutic intervention in children with JIA, based on the initial start of synthetic and biologic DMARDs (Step-down strategy), is superior to an approach based on treatment escalation conducted following the treat-to-target principle (Step-up strategy). The effectiveness of the two strategies will be assessed by comparing their ability to induce sustained clinical disease remission on/off treatment.

After screening of inclusion and exclusion criteria and recording of informed consent, patients will be randomized into two therapeutic arms: “Step up” or “Step down”. Patients in the Step-up arm will be treated according to a conventional strategy based on treatment escalation and driven by the treat-to-target strategy. Patients in the Step-Down arm will be treated with an early, combined, aggressive therapy for 6 months.

After the conclusion of the 12-month observation period of the trial, patients will be followed for up to 5 years for the evaluation of disease course, medication requirements, adverse events of medications, and long-term disease-related morbidity. The trial will enroll newly-diagnosed and DMARD-naïve children with a diagnosis of oligoarthritis or rheumatoid factor negative polyarthritis according to the ILAR criteria.

The desired sample size for the study is 260 patients. Enrollment will start as soon as Ethics Committee approvals are obtained. The PRINTO coordinating centre will offer assistance during the process of the Ethics Committees submission.

All PRINTO Italian centres will be invited to participate in this project with a dedicated survey in the next few days.

PharmaChild

The Pharmachild registry, started in 2011, is a pharmacovigilance project which aims at observing children with JIA for 3-10 years undergoing treatment with MTX or biologic agents in order to collect moderate, severe or serious adverse events occurred. This project is currently conducted by nearly 50 PRINTO centres worldwide and has now enrolled more than 10,000 unique patients.

Pharmachild has been funded by the European Union (EU) within the FP7 framework (contract number 260353, principal investigator Dr Nico Wulffraat, co-principal investigator Dr Nicolino Ruperto).

COLLABORATION WITH PHARMACEUTICAL COMPANIES

The Pharmachild protocol envisages the opportunity of a cooperation with pharmaceutical companies, which may want to use the data derived from Pharmachild for regulatory post-marketing surveillance obligations related to their product towards regulatory authorities. In this cases, PRINTO will MAINTAIN THE OWNERSHIP OVER THE DATA COLLECTED in order to continue to fulfill the ENCePP principles of transparency and scientific independence. All related possible revenues will be totally reinvested for the research needs of the project to support the prolongation of the
registry over the planned 3-10 years. List of companies which have agreed to cooperate with Pharmachild: - Bristol-Myers Squibb (Abatacept in JIA)

**ABIRISK**

**ABIRISK** (Anti-Biopharmaceutical Immunization: Prediction and Analysis of Clinical Relevance to Minimize the Risk), is a large EU project now completed (enrollment closed in 2016, analysis on-going), funded by the Innovative Medicines Initiative, with the aim to provide an integrated approach to investigate anti-drug antibody formation in patients treated with various type of biopharmaceuticals products (BPs). PRINTO has been the coordinator for Juvenile Idiopathic Arthritis cohort: 148 patients newly treated with BPs (Adalimumab, Etanercept or Tocilizumab) were enrolled in 24 PRINTO centres in 12 countries who collected the biologic samples (Serum and RNA) at start of therapy and follow-up visits during the first year of treatment. The samples, centralized at the PRINTO facilities in Genoa (Italy), were transferred to the ABIRISK consortium laboratories for anti-drug antibody formation and PK evaluation. The clinical data were collected in the PharmaChild registry online database.

**EPOCA**

PRINTO is glad to announce that all the 51 JAMAR papers included in a dedicated supplement of Rheumatology International on Patient’s Reported Outcomes (PROs) have been finally published on line. The following are the final details of the Supplement:

*Volume 38, Issue 1 Supplement, April 2018*

**Supplement: Cross-cultural Adaptation and Validation of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR) for the Assessment of the Disease Status in Children with Juvenile Idiopathic Arthritis: An International Effort by the Paediatric Rheumatology International Trials Organisation (PRINTO)**

*Rheumatology International - ISSN: 0172-8172 (Print) 1437-160X (Online)*

You can find all the manuscripts of the Supplement at the following link:

https://link.springer.com/journal/296/38/1/suppl/page/1

or also on the PRINTO website, in the publications section:

https://www.printo.it/publications/papers

The JAMAR supplement includes one paper for each cross-culturally adapted and validated version of the questionnaire (title example: The Italian version of the JAMAR, etc.) and a general introductive manuscript with the description of the methodological approach.

PRINTO finally cross-culturally adapted and validated the Juvenile Arthritis Multidimensional Assessment Report (JAMAR) questionnaire in 54 languages across 52 different countries members of the network.

A total of 9,021 JIA patients and 4822 healthy children were enrolled from the 49 countries that took part both in the cross-cultural adaptation phase and in the related validation and data collection: Algeria, Argentina, Belgium, Brazil, Bulgaria, Canada, Chile, Colombia, Croatia, Czech Republic, Denmark, Ecuador, Egypt, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, India, Islamic Republic of Iran, Israel, Italy, Latvia, Libya, Lithuania, Mexico, Netherlands, Norway, Oman, Paraguay, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Serbia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Thailand, Turkey, Ukraine, United Kingdom and United States of America. The introductory paper describes the overall methodology, while the results related to each country are fully described by the 282 different authors of the 49 individual manuscripts. The JAMAR was found to have satisfactory psychometric properties and it was thus demonstrated to be a reliable and valid tool for the multidimensional assessment of children with JIA.

The cross-cultural adaptation and validation of the JAMAR could have not been accomplished without the support and the cooperation of the PRINTO members in their local paediatric rheumatology centres, as well as the participation of the families of the JIA patients and healthy controls.

**SHARE**

The “Single Hub and Access point for paediatric Rheumatology in Europe” (acronym SHARE, project number 2011 1202; PI N. Wulffraat) aims to provide the European countries with recommendations for the care of children with rheumatic diseases. These recommendations are based on systematic literature reviews and on the surveys sent by PRINTO to individual centres belonging to its network all over the world. To identify the specific needs for the optimal care in PRD, PRINTO implemented an online survey, available at www.printo.it/SHARE. In april 2018, more than 260 paediatric rheumatic centres had already completed the questionnaire.

Thanks to this project, PRINTO has updated and renovated its website for families. The new site www.printo.it/pediatric-rheumatology offers scientific information regarding the pediatric rheumatic diseases (PRD), the list of centres dealing with PRD, and the list of the family associations in more than 60 languages.

In order to mirror the survey for physicians and have a clear picture of the standards of care from a patient/parent point of view, a dedicated survey has been prepared in a collaborative effort between Dr Nico Wulffraat and the ENCA (European Network for Children with Arthritis) members. The patient/parent survey has been translated in 18 languages. Currently, almost 1300 patients have completed the parent survey.
Eurofever Registry

The Eurofever Registry was promoted in 2008 by the work group of autoinflammatory diseases of the Paediatric Rheumatology European Society (PRES) and was supported by the Executive Agency for Health and Consumers (EAHC). The main objective of the project has been the creation of a registry of autoinflammatory diseases. Few years ago a section dedicated to Efficacy and Safety has been implemented and the registry is able to collect also longitudinal information. Up to date 4072 patients have been enrolled in the Registry from 62 different countries and enrollment is ongoing.

MYPAN

The MYPAN trial is an Open Label Randomised Controlled Trial of Mycophenolate Mofetil (MMF) Versus Cyclophosphamide (CYC) for the Induction of Remission of childhood PAN sponsored by University College London and coordinated by the Children Hospital in Liverpool and PRINTO (PI Dr P. Brogan). MYPAN investigates the comparative efficacy and safety of MMF (experimental treatment) vs CYC (standard treatment) for induction of remission of childhood PAN. This is the first ever randomized trial for childhood PAN. Since the enrollment period has been extended and will be officially closed on June 30th, 2018, we ask all the participating centres to make a last effort and try to recruit the last patients in the study.

Patients enrolled in the PRINTO projects

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**PRINTO overall enrollment status**

**Latest PRINTO papers**


A web-based collection of genotype-phenotype associations in hereditary recurrent fevers from the Eurofever registry.

Orphanet J Rare Dis 2017 Oct 18;12(1):167

Ruperto N, Brunner HJ, Lovell DJ, Martini A for the Pediatric Rheumatology International Trials Organization (PRINTO) and the Pediatric Rheumatology Collaborative Study Group (PRCSG)
Extrapolation or controlled trials in paediatrics: the current dilemma.


An international delphi survey for the definition of the variables for the development of new classification criteria for periodic fever aphtous stomatitis pharingitis cervical adenitis (PFAPA)

Pediatr Rheumatol Online J 2018 Apr 18;16(1):27 PubMed


Subcutaneous golimumab for children with active polyarticular-course juvenile idiopathic arthritis: results of a multicentre, double-blind, randomised-withdrawal trial.


The Danish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The French Version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


Malagon C, Mosquera Pongutà AC, De Inocencio J, Consolaro A, Bovis F, Ruperto N for the Paediatric Rheumatology International Trials Organisation (PRINTO)

The Colombian Spanish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Croatian version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Czech version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Dutch version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)

Rheumatol Int 2018;38 (Suppl 1):S139–S146 PubMed
The Ecuadorian Spanish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)

The Egyptian Arabic version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)

The Estonian version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)

The Farsi version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)

The Finnish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)

The Flemish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)

The Afrikaans version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)

The German version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)

Preface to the Juvenile Arthritis Multidimensional Assessment Report (JAMAR) Supplement in Rheumatology International
Rheumatol Int 2018;38 (Suppl 1):S1–S3 PubMed
Trials Organisation (PRINTO)

The Mexican Spanish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Norwegian version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


Morel Ayala Z, Burgos-Vargas R, Consolaro A, Bovis F, Ruperto N for the Paediatric Rheumatology International Trials Organisation (PRINTO)

The Paraguayan Spanish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Polish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Portuguese version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Romanian version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Russian version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Serbian version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Slovak version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


Lovell DJ, Brunner HI, Ringold S, Weiss PF, Martin N, Consolaro A, Bovis F, Ruperto N for the Paediatric Rheumatology International Trials Organisation (PRINTO)

The American English version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Slovene version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


Ekelund M, Berntson L, Consolaro A, Bovis F, Ruperto N for the Paediatric Rheumatology International Trials Organisation (PRINTO)

The Swedish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Swiss French version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Thai version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Turkish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


Boyko Y, Hrytsiuk I, Consolaro A, Bovis F, Ruperto N for the Paediatric Rheumatology International Trials Organisation (PRINTO)

The Ukrainian version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Arabic version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Argentinian Spanish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Brazilian Portuguese version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)

Rheumatol Int 2018;38 (Suppl 1):S59–S66


Cross-cultural adaptation and psychometric evaluation of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR) in 54 languages across 52 countries: review of the general methodology


The British English version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Bulgarian version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Canadian version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Castilian Spanish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


Norambuena X, Consolaro A, Bovis F, Ruperto N for the Paediatric Rheumatology International Trials Organisation (PRINTO)

The Chilean Spanish version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


The Omani Arabic version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR)


A national cohort study on pediatric Behçet’s disease: cross-sectional data from an Italian registry.


Measuring Disease Damage and its Severity in Childhood-Onset Systemic Lupus Erythematosus.

Arthritis Care Res 2018 Feb 6, [Epub ahead of print] PubMed

Other news & events

ERN RITA : Bursaries for Junior Doctors 2018-2019

One of the objectives of ERN RITA is to build upon excellent current training activities and to support the development of the next generation of expertise within our 3 rare disease themes.
The ERN RITA budget for Year 2 includes 5 bursaries, available for junior doctors for up to a maximum of 1000 euros each. These awards are to support individuals’ participation in European training events or short secondments to ERN RITA HCPs to promote development of expertise.

Applicants are invited to submit a letter of request to the ERN Coordinator, Professor Andrew Cant, and must adhere to the following criteria:
- To include a detailed explanation of what the funding is to be used for
- How the applicant will benefit from the activity
- Why alternative funding source for the activity is unavailable to the applicant
- Date of activity (between 1st March 2018 to 28 February 2019)
- To include approval from the institute of the applicant

Each application shall be reviewed by the ERN RITA Executive Board. Closing dates for applications are 30 April 2018 and 14 September 2018. For any further information, please contact Dr MarcoGattorno at marcogattorno@gaslini.org

PRINTO membership
As of today, PRINTO has reached 1349 effective members in 630 centres from 88 countries.
If you wish to become a PRINTO member and receive regular updates about our research activity and invitations to our projects please go to: https://www.printo.it/contact/apply-membership
Your cooperation will be more than welcome and your effort will be essential for the research in the field of paediatric rheumatic diseases.

WELCOME ABOARD!

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