



Pædiatric **R**heumatology
International **T**rials **O**rganisation

33rd Newsletter | September 2023

[PRINTO General Assembly at the PReS Congress]

Dear Friends,

We are happy to invite all of you to the upcoming Annual PRINTO General Assembly at the PReS 2023 Congress, that will be held

Friday 29 September from 18.00 to 19.00 CET (Room name: Mees Room 2)

Here is the AGENDA:

- **Introduction (Alberto Martini)**
- **The PRINTO/PReS Research Grants (Fabrizio De Benedetti)**
- **Cross-cultural adaptation and validation of LoSQI in JLS (Clare Pain)**
- **Comparison of Kobayashi and Kawanet IVIg resistance scores - the KIWI study (Maria Vincenza Mastrolia)**
- **Optimizing Treatment in sJIA and MAS/Secondary HLH: the METAPHOR Project (Francesca Minoia)**
- **The PhGA consensus meeting (Veronika Rypdal)**
- **The Eurofever Registry and AID ongoing studies (Marco Gattorno)**
- **The HyperPED-COVID Registry (Roberta Caorsi)**
- **The DAISY study (Dragana Lazarevic)**
- **The STARS trial (Alessandro Consolaro)**
- **The CEST-JIA study (Giovanni Filocamo)**
- **The JIA classification study (Nicola Ruperto)**
- **Update on the PRINTO research activity (Nicola Ruperto)**

Giulia and Marco from the staff of the PRINTO Coordinating centre will be available at the **PRINTO booth** during the Congress and will be more than happy to meet you and discuss the network's projects and initiatives!

Thank you in advance for your participation, and see you in Rotterdam!

Alberto, Nicola and the staff of the PRINTO coordinating centre

Meet the PIs!

The PIs of the ongoing studies will be also available at the PRINTO booth for further clarifications on their projects and to meet already participating or potentially interested colleagues.

Detailed schedule of their presences will be available at the PRINTO booth, so do not miss your chance to meet the PIs!

Add the PRINTO GA to my calendar!



[PRINTO on going projects]



PIs: Nicolino Ruperto, Nico Wulffraat

PharmaChild 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. Pharmachild started in 2011 thanks to a European Union (EU) grant within the FP7 framework and has obtained the ENCePP Study Seal (ENCEPP).

As of today, **more than 9,000 patients have been enrolled from 88 centres in 31 countries.**

The PharmaChild project has also a sub-study on abatacept, in collaboration with Bristol Myers and Squibb.

Enrolment is still open, although no reimbursement for data entry is provided.



PI: Nicolino Ruperto

The JIA Classification study is a translational study that aims to validate, in a **prospective collection of at least 1,000 patients at disease onset**, the proposed PRINTO consensus classification criteria for JIA. This entails also the collection of biologic samples for ANA, anti CCP, RF, HLA B27 determinations and DNA analysis.

Enrollment is now closed and we have collected a total of **1514 patients** from **97 enrolling centres.**

Import of biological samples to PRINTO is also completed and samples analysis is ongoing.



PI: Alessandro Consolaro

The comparison of SStep-up and step-down therapeutic strategies in childhood ARthritiS trial (STARS) is a new interventional trial **aiming 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). At the moment we have 19 active centres and a total of 186 patients enrolled in Italy.

We are now opening sites also outside Italy to increase recruitment.



PI: Marco Gattorno

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**.

The registry collects information about the clinical picture, the onset of **complications**, the **treatment**, the current findings (laboratory and instrumental), **safety**, compliance to the therapy and the **quality of life**.

From 2009 to date, the **information of more than 5200 patients** have been collected from **127 centers** distributed in **44 countries** around the world.

Enrolment is still open, a reimbursement is being provided.

Seza Ozen is now coordinating a **new project** in order to **analyze longitudinally the data on FMF patients** and a new study on **DADA2** is ongoing.



PI: Dragana Lazarevic

The DAISY study (Applicability of standardized ultrasound examination to estimate disease activity in combination with JADAS and inflammation markers in JIA patients) **aims to investigate sensitivity and predictive value of the multi-biomarker panel** and to evaluate if it could be applied in limited number of joints in patients with oligo and polyarticular JIA course as a new disease activity tool and outcome measure.

This **multicenter international study** in JIA patients involves selected pediatric rheumatology centers with expertise in the ultrasound examination of joints. The coordinating centers are Nis (Serbia) and Genoa (Italy).

At the moment

we have **10 enrolling centres** and a total of **87 patients**.

CEST - JIA

PI: Giovanni Filocamo

The CEST-JIA study is an interventional trial aiming to compare the **safety and efficacy of adalimumab and etanercept originator molecules vs biosimilars** in the treatment of **poliarticular course JIA** as well as to evaluate **safety and efficacy of switching from originator biological**



PI: Marco Gattorno

HyperPED-COVID is a retrospective observational study.

Its principal aim is to capture the burden of this spectrum of hyperinflammatory conditions related to COVID-19 in children and young adults.

For this reason, a **joined PReS, ISSAID, ESID, ERN-RITA and PRINTO network's effort** has been started aimed to **collect standardized clinical data** of these patients in a **common registry**.

Primary endpoint of the project is to collect information on clinical presentation, laboratory parameters, clinical outcome and response to treatment of **patients with COVID-19 related hyperinflammation**.

As of today we have more than 1400 subjects enrolled in 58 sites worldwide.

It is still possible to join and to include your patients!

molecules to bsDMARDS and vice-versa in current clinical practice as per the local standard of care and according to international recommendation.

As of today we have 1 active centre with 17 subjects enrolled, but we are currently opening more sites in Italy.

Enrolments in PRINTO studies



[PRINTO publications]

More than 15 peer-reviewed manuscripts accepted and published in scientific journals with IF in the last 2 years! A special thanks to all co-authors!

Some titles?

[Baricitinib in juvenile idiopathic arthritis: an international, phase 3, randomised, double-blind, placebo-controlled, withdrawal, efficacy, and safety trial](#)

Ramanan AV, Quartier P, Okamoto N, Foeldvari I, Spindler A, Fingerhutová Š, Antón J, Wang Z, Meszaros G, Araújo J, Liao R, Keller S, Brunner HI, Ruperto N for the JUVE-BASIS investigators and the Paediatric Rheumatology International Trials Organisation *Lancet* 2023 Aug 12;402(10401):555-570

[Secukinumab in enthesitis-related arthritis and juvenile psoriatic arthritis: a randomised, double-blind, placebo-controlled, treatment withdrawal, phase 3 trial](#)

Brunner HI, Foeldvari I, Alexeeva E, Ayaz NA, Calvo Penades I, Kasapcopur O, Chasnyk VG, Hufnagel M, Žuber Z, Schulert G, Ozen S, Rakhimyanova A, Ramanan A, Scott C, Sozeri B, Zholobova E, Martin R, Zhu X, Whelan S, Pricop L, Martini A, Lovell D, Ruperto N for the Paediatric Rheumatology International Trials Organization (PRINTO) and the Pediatric Rheumatology Collaborative Study Group (PRCSG). *Ann Rheum Dis* 2023 Jan;82(1):154-160

[Patient-Reported Outcomes Among Patients Ages Two to Seventeen Years With Polyarticular-Course Juvenile Idiopathic Arthritis Treated With Subcutaneous Abatacept: Two-Year Results From an International Phase III Study](#)

Ruperto N, Lovell DJ, Berman A, Avila-Zapata F, Horneff G, Alessio M, Becker ML, Belot A, Burgos-Vargas R, Gamir ML, Goldenstein-Schainberg C, Scheibel IM, Terreri MT, Zemel

L, Zhuo J, Askelson M, Wong R, Martini A, and Brunner HI, for the Pediatric Rheumatology Collaborative Study Group and the Paediatric Rheumatology International Trials Organisation
Arthritis Care Res 2023 Aug;75(8):1804-1814

[Validity and Reliability of Four Parent/Patient-Reported Outcome Measures for Juvenile Idiopathic Arthritis Remote Monitoring](#)

van Dijkhuizen EHP, Ridella F, Naddei R, Trincianti C, Avrusin I, Mazzoni M, Sutera D, Ayaz NA, Penades IC, Constantin T, Herlin T, Oliveira SK, Rygg M, Sanner H, Susic G, Sztajn bok F, Varbanova B, Ruperto N, Ravelli A, Consolaro A for the Pediatric Rheumatology International Trials Organization (PRINTO)
Arthritis Care Res (Hoboken) 2023 Feb;75(2):391-400

[Breaking down the fences among registries on autoinflammatory diseases: the E-Merge project](#)

Y. Vyzhga, V. Hentgen, R. Caorsi, H. Wittkowski, M. Hofer, N. Ruperto, E. Lainka, K. Theodoropoulou, D. Foell, E. Mosci, M. Gattorno
Orphanet J Rare Dis 2023 Jul 17;18(1):191

[Juvenile idiopathic arthritis patients with positive family history of autoimmune thyroid disease might benefit from serological screening: analysis of the international Pharmachild registry](#)

van Straalen JW, Baas L, Giancane G, Grebenkina L, Brunner J, Vega-Cornejo G, Chasnyk VG, Harel L, Appenzeller S, Gervais E, de Roock S, Wulffraat NM, Ruperto N, Swart JF for the Paediatric Rheumatology International Trials Organisation (PRINTO)
Pediatr Rheumatol Online J 2023 Feb 21;21(1):19

[Development and External Validation of a Model Predicting New-Onset Chronic Uveitis at Different Disease Durations in Juvenile Idiopathic Arthritis](#)

van Straalen JW, Kearsley-Fleet L, Klotsche J, de Roock S, Minden K, Heiligenhaus A, Hyrich KL, de Boer JH, Lamot L, Olivieri AN, Gallizzi R, Smolewska E, Faugier E, Pastore S, Hashkes PJ, Herrera CN, Emminger W, Consolini R, Wulffraat NM, Ruperto N, Swart JF for the Paediatric Rheumatology International Trials Organisation (PRINTO), UK CAPS study, and German ICON study
Arthritis Rheumatol Vol. 75, No. 2, February 2023, pp 318-327



[PRINTO membership]

PRINTO has now reached **2038 effective members in 717 centres** in 94 countries worldwide.

If you wish to become a PRINTO member and receive regular updates and invitations to our research projects, click on the banner below or feel free to

contact PRINTO.

Join the network!

Your cooperation will be more than welcome and your effort will be essential for the research against the paediatric rheumatic diseases.

BECOME A MEMBER



[PRINTO Council]

Chairman

Alberto Martini, MD, Prof - Genoa, Italy

Counsellors

Tadej Avcin, MD, PhD - Ljubljana, Slovenia

Michael Hofer, MD, Prof - Lausanne, Switzerland

Seza Ozen, MD, Prof - Ankara, Turkey

Pierre Quartier, MD - Paris, France

Claudia Saad Magalhães, MD, Prof - Botucatu, Brazil

Joos Swart, MD - Utrecht, The Netherlands

Senior Scientist

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