

PRINTO PROJECTS

	JDM trial	Eurofever
Albania		
Argentina	15	20
Austria		5
Belgium	6	
Brasil	13	
Bulgaria		
Chile		
Croatia		5
Czech Republic	2	20
Denmark	2	29
El Salvador		
Estonia		
France	25	111
Georgia		9
Germany	3	84
Greece	1	
Hungary		
India		
Iran		
Israel	1	46
Italy	33	159
Kuwait		
Latvia	1	
Libya		1
Lithuania		1
Mexico	6	
Netherlands	4	60
Norway	2	
Oman		4
Poland		
Romania		7
Russia		12
Saudi Arabia		33
Serbia	1	
Slovakia	2	
Slovenia	4	5
Spain		11
Sweden	6	
Switzerland		49
Turkey		33
Un. Kingdom	2	196
USA	1	
Venezuela	5	
Total	135	900

Paediatric Rheumatology International
Trials Organisation (PRINTO)
IRCCS G. Gaslini Pediatrica II
Largo Gaslini, 5
16147 Genova - ITALY



August 2010

Paediatric Rheumatology International Trials Organisation (PRINTO)



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Nicola Ruperto, MD, MPH - Genova, Italy

IRCCS G. Gaslini
Pediatrica II - PRINTO
Largo Gaslini, 5
16147 Genova, ITALY

Tel: +39-010-38-28-54 or +39-010-39-34-25

Fax +39-010-39-33-24 or +39-010-39-36-19

E-mail: printo@ospedale-gaslini.ge.it

www.printo.it

www.pediatric-rheumatology.printo.it

17th NEWSLETTER

PReS Congress 2010 Valencia, Spain
Friday, September 10, 2010 at **14.00-15.30**

Sala Rodrigo

Agenda for the annual PRINTO workshop

- Introduction (A. Martini)
- Update on PRINTO Projects (N. Ruperto)
- The PharmaChild Project (N. Wulffraat)
- The PRES EuroFever project (M. Gattorno)
- The EPOCA and MAS study (A. Ravelli)
- CARRA: progress and future plans (N. Ilowite)

New onset JDM trial:

- prednisone (PDN) versus
- PDN plus Cyclosporine A versus
- PDN plus methotrexate.

The trial is almost close to complete enrolment with 135 patients recruited from 55 centres in 23 countries (see table next page). The analysis is planned for 2011; payment for patients' contribution will start soon after. **No major safety concern identified so far**

The PharmaChild Project: to evaluate the long term safety and efficacy profiles of treatment with biologic agents in JIA. The project financed by the European Union (PI Dr N. Wulffraat) will officially start in year 2011. A total of 185 centres in 51 countries have expressed the willingness to collaborate and will be contacted soon.

The PRES Eurofever project. The PReS Autoinflammatory Diseases' Working Group financed by the EU (PI Dr M. Gattorno), is now fully enrolling. Data can be collected on line at www.printo.it logging in the "member area". A total of 900 patients (see table) have been entered into the on line database. Thanks to a grant from the PRINTO Advisory Council, participating centres will receive 50 € for each patient with a rare monogenic disease and 25 € with a more common autoinflammatory disease enrolled.

The EPOCA study. Participating centres are asked to translate and cross-culturally validate the parent and the child version of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR) and to assess 100 consecutive JIA patients and healthy controls. The national language translations of the JAMAR will be published in a supplement of Clinical and Experimental Rheumatology. The aim of this study is twofold:

- 1) to foster regular use of parent/patient-reported outcomes in paediatric rheumatology practice;
- 2) to obtain information about the frequency of ILAR categories, treatment modalities, and current outcome of JIA around the world.

The MAS criteria study. The second phase of the project, which is aimed to collect data from patients with MAS and control patients, is ongoing. Investigators who are interested to participate in the study are asked to include the clinical and laboratory data from the following 3 groups of patients:

1. Patients with systemic JIA who had an episode of MAS, diagnosed and treated as such by the attending physician, and were seen from January 2002 to date;
2. An approximately equal number of instances of active disease (in the absence of MAS) in children with systemic JIA seen in the same period;
3. An approximately equal number of children with an acute febrile infection, admitted to the hospital (inclusion of these patients is optional).

A website for internet-based data collection is currently in preparation by the PRINTO staff and will be ready by the mid of September.

Membership: 622 effective members (27% increase) in 323 centres (17% increase) from 52 countries.

Recent PRINTO publications

For reprints go to www.printo.it and click on papers.

- Saad-Magalhães C, Pistorio A, Ravelli A, Filocamo G, Viola S, Brik R, Mihaylova D, ten Cate R, Andersson-Gare B, Ferriani V, Minden K, Hashkes PJ, Rygg M, Sauvain MJ, Venning H, Martini A, Ruperto N, for PRINTO. Does removal of aids/devices and help make a difference in the Childhood Health Assessment Questionnaire Disability Index? *Ann Rheum Dis* 2010;69(1):82-87.
- Ruperto N, Lovell DJ, Cuttica R, Woo P, Meiorin S, Wouters C, Silverman ED, Balogh Z, Henrickson M, Davidson J, Foeldvari I, Imundo L, Simonini G, Oppermann J, ShenYK, Visvanathan S, Fasanmade A, Mendelsohn A, Martini A, Giannini EH, for PRINTO and PRCSG. Long-term efficacy and safety of infliximab plus methotrexate for the treatment of polyarticular course juvenile rheumatoid arthritis: findings from an open-label treatment extension. *Ann Rheum Dis* 2010;69:718-22.
- Foell D, Wulffraat N, Wedderburn LR, Wittkowski H, Frosch M, Gerß J, Stanevicha V, Mihaylova D, Ferriani V, Kanakoudi Tsakalidou F, Foeldvari I, Cuttica R, Gonzalez B, Ravelli A, Khubchandani R, Oliveira S, Armbrust W, Garay S, Vojinovic J, Norambuena X, Gamir ML, García-Consuegra J, Lepore L, Susic G, Corona F, Dolezalova P, Pistorio A, Martini A, Ruperto N, Roth J, for PRINTO . Methotrexate withdrawal at 6 vs 12 months in juvenile idiopathic arthritis in remission: a randomized clinical trial. *JAMA* 2010;303:1266-1273.
- Ruperto N, Ozen S, Pistorio A, Dolezalova P, Brogan P, Cabral DA, Cuttica R, Khubchandani R, Lovell DJ, O'Neil KM, Quartier P, Ravelli A, Iusan SM, Filocamo G, Saad Magalhães C, Unsal E, Oliveira S, Bracaglia C, Bagga A, Stanevicha V, Magni Manzoni S, Pratisdov P, Lepore L, Espada G, Kone Paut I, Zulian F, Barone P, Bircan Z, del Rocio Maldonado M, Russo R, Vilca I, Tullus K, Cimaz R, Horneff G, Anton J, Garay S, Nielsen S, Barbano G,

Martini A, for PRINTO. EULAR/PRINTO/PRES criteria for Henoch-Schönlein purpura, childhood polyarteritis nodosa, childhood Wegener granulomatosis, and childhood Takayasu arteritis: Ankara 2008. Part I: overall methodology and clinical characterisation. *Ann Rheum Dis* 2010;69:790-797.

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- Ruperto N, Lovell DJ, Quartier P, Paz E, Rubio-Pérez N, Silva CA, Abud-Mendoza C, Burgos-Vargas R, Geroni G, Melo-Gomes JA, Saad-Magalhães C, Chavez J, Huemer C, Kivitz A, Blanco FJ, Foeldvari I, Hofer M, Horneff G, Huppertz HI, Job Deslandre C, Loy A, Minden K, Punaro M, Flores Nunez A, Sigal LH, Block AJ, Nys M, Martini A, Giannini EH, for PRINTO and PRCSG. Long-Term Safety and Efficacy of Abatacept in Children with Juvenile Idiopathic Arthritis. *Arthritis Rheum* 2010;62(6):1792-1802.
- Ruperto N, Bazso A, Pistorio A, Ravelli A, Filocamo G, Hernandez Huirache HG, Rodriguez Lozano AL, Pringe AB, Vilca I, Martini A, for PRINTO. Agreement between multi-dimensional and renal-specific response criteria in patients with juvenile systemic lupus erythematosus and renal disease. *Clin Exp Rheumatol* 2010;28:424-433.

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- Ruperto N, Giannini EH, Pistorio A, Brunner HI, Martini A, Lovell DJ. Is it time to move to active comparator trials in juvenile idiopathic arthritis? A review of current study designs. *Arthritis Rheum* 2010; July 26. [Epub ahead of print]