

PRINTO PROJECTS

	JDM trial	Eurofever	JIA MAS
Albania		1	
Argentina	15	24	35
Australia		10	
Belgium	6	13	
Bosnia			2
Brazil	13	5	28
Canada			19
Chile		1	
China			20
Croatia		8	6
Czech	2	44	
Denmark	2	113	6
France	26	233	29
Georgia		9	6
Germany	4	177	13
Greece	2	30	2
Hungary		2	
India		3	23
Israel	1	142	8
Italy	34	443	341
Japan			2
Kuwait			
Latvia	1	2	46
Libya		1	37
Lithuania		1	
Mexico	6		
Netherlands	4	75	8
Norway	2		
Oman		4	
Poland			
Romania		13	
Russia		20	15
Saudi Arabia		34	2
Serbia	1	3	6
Slovakia	2	1	
Slovenia	4	9	14
Spain		83	28
Sweden	6		
Switzerland		57	1
Turkey		149	129
Un. Kingdom	2	260	
USA	1		78
Venezuela	5		8
Total	139	1970	912

Paediatric Rheumatology International
Trials Organisation (PRINTO)
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August 2011

Paediatric Rheumatology INTERNATIONAL TRIALS Organisation (PRINTO)



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PRoS Congress 2011 Bruges, Belgium
Saturday, September 17, 2011 at **12.45-13.30**
Room Ambassadeur, Out Sint-Jan
Pharmachild Project Meeting (N. Wulffraat)

Saturday, September 17, 2011 at **13.30-15.00**
Concert Hall

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)

New onset JDM trial:

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

The enrollment of the trial is now closed with 139 patients recruited from 55 centres in 23 countries (see table next page). The analysis is planned to begin in January 2012 upon receiving data of one year of follow-up from every patient. Payment to sites will start next year when the database is closed. **No major safety concern identified since last year.**

The PharmaChild Project: This project has the aim to create a registry of the potential serious adverse events in JIA patients treated with biologics and/or MTX on a long-term period. The project financed by the European Union (PI Dr N. Wulffraat) officially started in April 2011. A first communication regarding EC submission has been spread to all the PRINTO members. Doctors willing to participate to this project should

complete a simple questionnaire at the following link
<https://www.printo.it/Pharmachild/investigator/>
by logging in with the personal log-in data received by PRINTO through a separate e-mail.

The PRES Eurofever project. The PRoS Autoinflammatory Diseases' Working Group financed by the EU (PI Dr M. Gattorno), is fully enrolling. Data can be collected on line at www.printo.it logging in the "member area". A total of 1970 patients (see table) have been enrolled (+120% with respect to last year). Thanks to a grant support from PRINTO Advisory Council and a liberal contribution from a pharmaceutical company, participating centres will receive 50 € for each complete patient with a rare monogenic disease and 25 € with a more common autoinflammatory disease enrolled.

The EPOCA study. EPidemiology, treatment and Outcome of Childhood Arthritis: the study is aimed at photographing the current status of children with JIA across continents and countries. Participating centres are asked firstly to translate and cross-culturally validate the parent and child versions of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR) and secondly 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. Already 35 countries of the PRINTO network have almost completed the translation of the JAMAR into their national languages. The data collection phase will start in the fall through a dedicated web database on the PRINTO member area.

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. Data collection refers to 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 total of 223 patients from group 1, 368 from group 2 and 321 from group 3 have been enrolled via the PRINTO database system.

We foresee to close the enrollment at the end of September.

Membership: 747 effective members (20% increase) in 405 centres (25% increase) from 77 countries.

Recent PRINTO publications

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

- Visvanathan S, Wagner C, Marini JC, Lovell DJ, Martini A, Petty R, Cuttica R, Woo P, Espada G, Gattorno M, Apaz MT, Baildam E, Fasth A, Gerloni V, Lahdenne P, Quartier P, Saurenmann R, Travers S, Mendelsohn A, Xu S, Giannini EH, Ruperto N for the Paediatric Rheumatology International Trials Organization (PRINTO) and the Pediatric Rheumatology Collaborative Study Group (PRCSG). The effect of infliximab plus methotrexate on the modulation of inflammatory disease markers in juvenile idiopathic arthritis: analyses from a randomized, placebo-controlled trial. **Pediatr Rheumatol Online J 2010;8:1-24.**
- Ruperto N, Pistorio A, Ravelli A, Rider LG, Pilkington C, Oliveira S, Wulffraat N, Espada G, Garay S, Cuttica R, Hofer M, Quartier P, Melo-Gomes J, Reed AM, Wierzbowska M, Feldman BM, Harjacek M, Huppertz HI, Nielsen S, Flato B, Lahdenne P, Michels H, Murray KJ, Punaro L, Rennebohm R, Russo R, Balogh Z, Rooney M, Pachman LM, Wallace C, Hashkes P, Lovell DJ, Giannini EH, Martini A, for PRINTO and PRCSG. The Pediatric Rheumatology International Trials Organization provisional criteria for the evaluation of response to therapy in juvenile dermatomyositis. **Arthritis Care Res 2010;62:1533-1541.**
- Ruperto N, Lovell DJ, Li T, Sztajn bok F, Goldenstein-Schainberg C, Scheinberg M, Penades I, Fischbach M, Orozco J, Hashkes PJ, Hom C, Jung L, Lepore L, Oliveira S, Wallace C, Alessio M, Quartier P, Cortis E, Eberhard A, Simonini G, Lemelle I, Chalom E, Sigal LH, Block A, Covucci A, Nys M, Martini A, Giannini EH, for PRINTO and PRCSG. Abatacept improves health-related quality of life, pain, sleep quality and daily participation in subjects with juvenile idiopathic arthritis. **Arthritis Care Res 2010;62:1542-1551.**

- 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;62:3131-3139.**
- Toplak N, Dolezalová P, Constantin T, Sedivà A, Pašić S, Čižnar P, Wolska-Kušnierz B, Harjaček M, Stefan M, Ruperto N, Gattorno M, Avčin T and Eastern/Central European autoinflammatory collaborating group for the Paediatric Rheumatology International Trials Organisation (PRINTO) and Eurofever Project. Periodic fever syndromes in Eastern and Central European countries: results of a pediatric multinational survey. **Pediatr Rheumatol Online J 2010;8:29.**
- Ruperto N, Pistorio A, Ravelli A, Hasija R, Guseinova D, Filocamo G, Demirkaya E, Malattia C, Martini A, for the Paediatric Rheumatology International Trials Organisation (PRINTO). Criteria to define response to therapy in paediatric rheumatic diseases. **Eur J Clin Pharmacol 2011;67(Suppl 1):S125-S131.**
- Ruperto N, Martini A, for the Paediatric Rheumatology International Trials Organisation (PRINTO). Networking in pediatrics: the example of the Pediatric Rheumatology International Trials Organisation (PRINTO). **Archives Dis Child 2011;96:596-601.**
- Wallace CA, Giannini EH, Huang B, Itert L, Ruperto N for the Childhood Arthritis and Rheumatology Research Alliance (CARRA), the Pediatric Rheumatology Collaborative Study Group (PRCSG), and the Pediatric Rheumatology International Trials Organisation (PRINTO). American College of Rheumatology provisional criteria for defining clinically inactive disease in select categories of juvenile idiopathic arthritis. **Arthritis Care Res 2011;63:929-936.**

- Consolaro A, Ruperto N, Pistorio A, Lattanzi B, Solari N, Galasso R, Pederzoli S, Varnier GC, Dolezalova P, Alessio M, Burgos-Vargas R, Vesely R, Martini A, Ravelli A, for the Paediatric Rheumatology International Trials Organisation (PRINTO). Development and initial validation of composite parent and child centered disease assessment indices for juvenile idiopathic arthritis. **Arthritis Care Res 2011; epub ahead of print.**
- Hasija R, Pistorio A, Ravelli A, Demirkaya E, Khubchandani R, Guseinova D, Malattia C, Canhao H, Harel L, Foell D, Wouters C, De Cunto C, Huemer C, Kimura Y, Mangge H, Minetti C, Nordal EB, Philippet P, Garozzo R, Martini A, Ruperto N, for the Paediatric Rheumatology International Trials Organisation (PRINTO). Therapeutic approaches for the treatment of new onset and flared juvenile dermatomyositis: an international multicenter PRINTO study. **Arthritis Rheum 2011; epub ahead of print.**