

## PRINTO PROJECTS

	JDM trial	Vasculitis	MTX JIA
Albania		5	
Argentina	12	69	27
Austria		5	
Belgium	2		
Brasil	10	118	33
Bulgaria		8	20
Chile		20	18
Croatia		8	4
Czech Republic	2	7	5
Denmark	2	141	1
El Salvador		19	
Estonia		5	
France	9	67	9
Georgia		8	2
Germany	2	27	36
Greece		20	17
Hungary			1
India		48	9
Iraq		1	
Israel	1	123	8
Italy	18	274	35
Kuwait			2
Latvia	1	29	23
Libya		1	
Mexico	3	12	2
Netherlands	4	10	47
Norway	2		
Peru		14	
Poland		3	1
Portugal			3
Romania		59	
Russia		7	2
Saudi Arabia		8	
Serbia	1	5	16
Slovakia	2	2	4
Slovenia	1	1	
Spain		18	16
Sweden	4	2	1
Switzerland			4
Turkey		214	2
Un. Kingdom	1	35	16
USA	1	6	
Venezuela	4		
<b>Total</b>	<b>82</b>	<b>1399</b>	<b>364</b>

Paediatric Rheumatology International  
Trials Organisation (PRINTO)  
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## Paediatric Rheumatology International Trials Organisation (PRINTO)



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## PReS Congress 2008 London UK

Monday, September 15, 2008 at **13.30-14.30**

Agenda for the annual PRINTO workshop

- Challenges of conducting clinical trials in rare diseases (A. Martini)
- Update on PRINTO Projects (N. Ruperto)
- The PRES EuroFever project (M. Gattorno)

### New onset JDM trial:

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

The trial is now fully enrolling! As of today 80 patients from 19 countries (see table next page) have been enrolled. Other 71 patients could not be enrolled due to lack of inclusion criteria (mainly referral delays).

A total of 103 centres in 30 countries have now obtained ethics committee approval.

**No major safety concern identified so far**

### PRES/PRINTO/EULAR vasculitides registry:

The PReS Vasculitis Working Group, in collaboration with PRINTO (EULAR support) designed the registry to validate the recently developed "EULAR/PReS endorsed criteria for the classification of childhood vasculitides". We have enrolled 1,388 children (855 HSP, 237 PAN, 69 WG, 101 TA, 126 UCV) from 88 centres in 34 countries.

**Enrollment is NOW OVER.**

**We will proceed with the related per patient payment, by the end of the year**

**The PRES Eurofever project.** The PReS Autoinflammatory Diseases' Working Group, in collaboration with PRINTO designed a survey to set up a series of Registries for the different Autoinflammatory diseases. The project has now been financed by the EU and will be implemented soon.

### Genomics and Pediatric Rheumatic Diseases

**survey:** PRINTO designed the present survey to identify centres which have families with paediatric rheumatic diseases (PRD) where more cases of the same disease (e.g. JIA or JSLE or JDM etc) are present among brothers and/or sisters (affected sib pairs). A total of 273 families with JIA sibs and 109 with other PRD have been identified. We are now proceeding with DNA collection that will be limited to 60 JIA families.

**MTX withdrawal:** to determine if the time to discontinue MTX (6 versus 12 months) in JIA with inactive disease, influences the time to relapse. A total of 365 patients have been enrolled. We have also completed the collection of the serum and whole blood samples. **The related payment has been postponed and will be done by the end of the year**

**Membership:** 377 effective members in 208 centres from 46 countries.

### Recent PRINTO publications

For reprints go at [www.printo.it](http://www.printo.it) and click on papers.

- Ruperto N, Lovell DJ, Cuttica R, et al for PRINTO/PRCSG. A randomized, placebo-controlled trial of infliximab plus methotrexate for the treatment of polyarticular course juvenile rheumatoid arthritis. *Arthritis Rheum* 2007;56:3096-3106

- Ruperto N, Bazso A, Ravelli A, et al for PRINTO. Review: PRINTO. *Lupus* 2007;16:670-676
- Ruperto N, Ravelli A, Pistorio A, et al for PRINTO/PRCSG. The Provisional PRINTO/ACR Disease Activity Core Set for the evaluation of response to therapy in JDM: A Prospective validation study. *Arthritis Rheum* 2008;1:4-13.
- Céspedes-Cruz A, Gutiérrez-Suárez R, Pistorio A, et al for PRINTO/PRCSG. Methotrexate improves the health-related quality of life of children with JIA. *Ann Rheum Dis* 2008;67:309-314.
- Ruperto N, Martini A, for PRINTO. Network in pediatric rheumatology: the example of PRINTO. *Georgian Med News* 2008;156:68-74.
- Ruperto N, Lovell DJ, et al for PRINTO/PRCSG. Performing trials in children with rheumatic diseases: comment on the editorial by Lehman. *Arthritis Rheum*; 2008; 58:1201-1206.
- Ruperto N, Meiorin S, Iusan MS, et al for PRINTO. Consensus procedures and their role in pediatric rheumatology. *Current Rheumatology Reports* 2008, 10:142-146.
- Meiorin S, Pistorio A, Ravelli A, et al for PRINTO. Validation of the Childhood Health Assessment Questionnaire in active juvenile systemic lupus erythematosus. *Arthritis Rheum* 2008; 59:1112-1119.
- Ruperto N, Pistorio A, Ravelli A, et al for PRINTO. Reply to the letter by Rider et al. *Arthritis Rheum* 2008;59:1198-1199.
- Ruperto N, Lovell DJ, Quartier P, et al for PRINTO/PRCSG. Efficacy and safety of abatacept in children with JIA: A randomized, double-blind, placebo-controlled withdrawal trial. *Lancet* 2008; 372(9636):383-391.
- Lovell DJ, Ruperto N, Goodman S, et al for PRCSG/PRINTO. A Randomized, Placebo-Controlled Trial of Adalimumab with and without Methotrexate in Children with Polyarticular JRA. *NEJM* 2008;59:810-820.