

NOVEMBER 1999

PRINTO PROJECTS

COUNTRIES	PRINTO member/ centres	MTX trial enrolled/ non-resp.	Quality of life in JCACHAQ/ CHQ
Argentina			
Australia	1/1		
Austria	2/2		20
Belgium	4/3	5/1	5
Brazil	8/7		20
Chile	1/1		20
Croatia	1/1		20
Czech Republic	7/5	7	24
Denmark	3/3		20
Finland	5/2	2	22
France	8/8	5	5
Germany	8/7	4	22
Greece	6/4		20
Hungary	2/1		20
Ireland (North)	1/1		
Israel	7/6	1	21
Italy	25/13	75/6	742
Korea (South)	1/1	1	163
Latvia	1/1		
Lithuania	1/1		
Luxembourg	1/1		
Mexico	2/1		21
Netherlands	6/3	16/6	16
Norway	7/3	10	21
Poland			
Portugal	1/1		20
Russia	2/1		
Slovakia	4/4	8/1	28
Spain	6/4	13/1	33
Sweden	3/3	3	3
Switzerland	2/2	4	4
Turkey	1/1		20
Un. Kingdom	11/9	46/8	142
Yugoslavia	1/1		20
USA	1/1	7/3	7
Totals (25)	140/103	203/26	1479
Sample size		~700/230	

“Paediatric Rheumatology International
Trials Organisation - PRINTO”
IRCCS Policlinico S. Matteo
Dipartimento di Scienze Pediatriche
Piazzale Golgi, 2
27100 Pavia - ITALY



AIR MAIL/PRINTS/
/VIA AEREA/STAMPE

Paediatric Rheumatology
International Trials
Organisation - **PRINTO**



ADVISORY COUNCIL

Chairman

Alberto Martini, MD, Prof - Pavia, Italy

Counsellors

Boel Andersson Gäre, MD, PhD - Jönköping, Sweden

Wietse Kuis, MD, PhD - Utrecht, Netherlands

Anne-Marie Prieur, MD - Paris, France

Patricia Woo, MD, FRCP, PhD - London, United Kingdom

Secretary/ Trials Co-ordinator

Nicola Ruperto, MD, MPH - Pavia, Italy

Research Assistant

Lucy West, BSc - Pavia, Italia

PRINTO, IRCCS Policlinico S. Matteo, Clinica Pediatrica

P.le Golgi, 2 - 27100 Pavia, ITALY

Tel: +39-0382-50-20-25

Fax +39-0382-50-20-26 or +39-0382-52-87-62

E-mail: nruperto@smatteo.pv.it

Internet: <http://www.medit.it/printo/>

III NEWSLETTER

Membership: We have now 140 effective members in 103 centres in 33 countries.

Methotrexate (MTX) trial (medium vs high dose) in the idiopathic arthritides of childhood (IAC): the goal of the trial is to assess the efficacy and safety of a 6 months course of parenteral MTX in **MEDIUM** (15 mg/m²/once a week max dose 20 mg/once a week) versus **HIGH** dose (30 mg/m²/once a week; max dose 30 mg/once a week) in children who failed a standard dose MTX (8-12.5 mg/m²/once a week for 4-6 months). **59 centres** in **21** countries have now obtained Ethics Committee approval. A total of **203 patients** have been enrolled in the screening phase with **27** patients randomised to higher dose of MTX. The trial is proceeding extremely well!!

PLEASE REMEMBER TO RECRUIT EVERY PATIENTS NEWLY STARTED ON METHOTREXATE!!

Quality of life project in the IAC - the Childhood Health Assessment Questionnaire (CHAQ) and the Child Health Questionnaire (CHQ): goal of the project is to cross-cultural adapt and validate the CHAQ and CHQ in all languages of the PRINTO members. This will constitute the starting point for standardised functional, physical and psychosocial assessment in

future clinical trials in the pediatric rheumatic diseases. The project is proceeding very well with the translations completed in **33** countries and **1479** patients collected. Next phase will be data collection for 60 healthy children and 60 children with JCA to be completed by **MARCH, 2000**, to allow publication on Clin Exp Rheumatol by the end of year 2000.

Cyclosporine project: The PRINTO and the PRCSG are conducting a Phase IV post-marketing surveillance study of cyclosporine-A in patients with polyarticular course IAC. A total of **170 patients (350 forms)** have been enrolled from 13 different countries. A reimbursement for the effort has been sent to all participating centres.

Future studies: PRINTO is now conducting surveys to evaluate the feasibility of 2 potential new trials in IAC patients:

Phase II trial of a biologic agent in children with polyarticular course IAC

Phase III trial of a NSAID in children with IAC.

The list of countries to be contacted has been decided by the pharmaceutical companies.

Paediatric Rheumatology European

Society (PRES): PRES has been established during the 1999 Pediatric Rheumatology European conference. It is a non-profit making organisation. Its aims are to promote the knowledge of pediatric rheumatic diseases, stimulate research in the field, disseminate such knowledge at meetings, and provide training and guidelines in clinical practice. **PRES** will represent pediatric rheumatologists in European Union Organisations, and other professional societies.

PRES will hold an Annual Scientific Meeting, during Membership requires active clinical or research interest in pediatric rheumatology. It will provide the opportunity to be informed on up-to-date clinical, training and scientific developments in this speciality, collaborative research, and allied scientific meetings. Members will be entitled to a discount on registration fees at **PRES** scientific meetings, and the right to vote at the annual general meeting. The annual membership fee is currently set at 50 Euros (or if not possible the equivalent in your currency), 25 for training fellows (certificate required) and health professionals.

If you are interested in joining **PRES** please send back **THIS NEWSLETTER** to:

ROLANDO CIMAZ, MD, PRES Treasurer
Paediatric Department, Via Commenda 9
20122 Milano - **ITALY**

Remember to include in the envelope a bank check for the amount of **50 EUROS** payable to:

DR ROLANDO CIMAZ FOR PRES
Credit card payment is not yet available.
