PRINTO PROJECTS

COUNTRIES	PRINTO member/ centres	No of pts enrolled MTX trial	No. of pts enrolled Quality of life in JCA project CHAQ/CHQ
Argentina	2/2		124
Austria	2/2	2	134
Belgium	4/3	17	199
Brazil	8/6	49	471
Bulgaria	1/1	5	137
Chile	1/1		126
Croatia	1/1		139
Czech Republic	7/5	18	150
Denmark	3/2		139
Finland	5/2	9	161
France	9/8		500
Georgia	1/1		115
Germany	8/7	12	197
Greece	6/4		143
Hungary	2/1		127
Israel	7/6	10	144
Italy	25/13	175	1192
Korea (South)	1/1	2	221
Latvia	2/2		141
Mexico	3/1	17	182
Netherlands	6/4	42	180
Norway	7/3	19	148
Poland	1/1		30
Portugal	1/1		130
Russia	2/1		146
Slovakia	4/4	16	119
Spain	8/6	26	149
Sweden	3/3	6	129
Switzerland	3/3	19	147
Turkey	1/1	16	145
Un. Kingdom	12/10	165	440
Yugoslavia	1/1		139
USA		8	
Totals	**150/110**	**633**	**6,644**

"Pediatric Rheumatology International Trials Organisation - PRINTO"
IRCCS Policlinico S. Matteo
Dipartimento di Scienze Pediatriche
Piazzale Golgi, 2
27100 Pavia - **ITALY**

AUGUST 2001

Paediatric Rheumatology International Trials Organisation

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/

European Union grant no. QLG1-CT-2000-00514

VI NEWSLETTER

VIII European Paediatric Rheumatology Congress (Utrecht, September 26-30, 2001)

a PRINTO workshop will be held at the PRES meeting

September 29, 2001

All the PRINTO members, and interested people, are invited to participate.

The agenda will be as follows:

- Introduction (Alberto Martini)
- PRINTO projects update (Nicola Ruperto)
- Training session on outcome assessment in juvenile systemic lupus erythematosus and juvenile dermatomyositis (Angelo Ravelli, Kevin J. Murray)
- Meeting of the PRINTO national co-ordinators

Membership: We have now 150 effective members in 110 centres in 32 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/m^2/once a week max dose 20 mg/once a week) versus **HIGH** dose (30 mg/m^2/once a week; max dose 30 mg/once a week) in children who failed a standard dose MTX (8-12.5 mg/m^2/once a week for 4-6 months). **62 centres** in **20** countries have now obtained Ethics Committee approval. A total of **633 patients** have been enrolled in the screening phase with 83 patients randomised to higher dose of MTX.

ENROLLMENT FOR THE TRIAL IS OVER AS OF MARCH 31, 2001

STOP PATIENT ENROLLMENT!!

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. Data collection is now over in **32** countries with **6,644** patients collected. Results will be published in a supplement on Clin Exp Rheumatol in year 2001.

Core sets of outcome measures and definition of improvement for juvenile systemic lupus erythematosus (JSLE) and juvenile dermatomyositis (JDM). (Contract EU QLG1-CT-2000-00514).

Aim of this new project is to establish:

a JSLE and JDM core sets of outcome measure

a JSLE and JDM definitions of improvement to be used in future clinical trials.

AIM 1 has already been accomplished with several emails survey and a consensus conference held on March 31 April 3, 2001 at the Almo Collegio Borromeo, in Pavia, Italy. The meeting was attended by the PRINTO national co-ordinators. The results of the first phase will be presented during the PRINTO workshop.

AIM 2 will be reached through a large data collection and a second consensus conference to be held in 2003. You should have received by now the case report forms for data collection. During the PRINTO workshop we give a training session to teach how to assess patients with JSLE and JDM and complete the case report forms.

IMPORTANT this time PRINTO has obtained funds from the European Union to pay approximately **400 EURO** for each of the 500 patients you will send to Pavia, Italy.

The process is similar to that has been used for the juvenile arthritis definition of improvement (Giannini EH, Ruperto N, Ravelli A, Lovell DJ, Felson DT, Martini A: Preliminary definition of improvement in juvenile arthritis. Arthritis Rheum 1997; 40:1202-9).

A single definition of improvement for JSLE and JDM, will facilitate the standardisation, conduct, interpretation and efficiency of future clinical trials and meta-analyses. It is anticipated that these definitions of improvement might also be useful to physicians to decide if a child has responded adequately to therapy in routine clinical practice. The successful accomplishment of this project will therefore set the basis for planning future clinical trials for new therapeutic options for JSLE and for JDM patients.