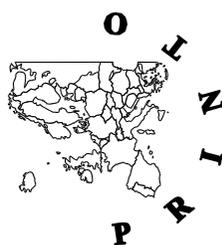


PRINTO

CURRENT

COUNTRIES	PRINTO MEMBERS	MTX TRIAL no. of pts screened	Translations CHAQ/CHQ
Austria	1		in progress
Belgium	2	in progress	done
Croatia	1		in progress
Czech Republic	5	3	done
Denmark	1		
Finland	2	in progress	done
France	6	in progress	done
Germany	7	in progress	done
Greece	1		
Hungary	1		in progress
Israel	2		
Italy	12	20	done
Netherlands	3	7	done
Norway	3	4	done
Portugal	1		done
Russia	1		in progress
Slovakia	4	in progress	done
Spain	4	3	done
Sweden	2	in progress	done
Switzerland	2		done
Turkey	1		
Un. Kingdom	6	5	done
Yugoslavia	1		
Totals (23)	69	42	14
Sample size		~700	

“Pediatric Rheumatology International Trials Organisation”
 IRCCS Policlinico S. Matteo
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AIR MAIL
 PRINTS

“Pediatric Rheumatology International Trials Organisation”



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Advisory Council (AC) II meeting (Pavia, Italy, February 5-7, 1999). The council members considered the current status of ongoing projects, and were encouraged by the European-wide membership.

Membership: We have now 69 effective members in 23 European 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 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, administered for 4-6 months). **32 centres** in 12 countries have now obtained ethics committee approval for participation at the trial. Patient's enrollment have just started. A total of **42 patients** have been enrolled in the screening phase with 3 patients already randomised to higher dose of MTX. This is a very encouraging start but because of the delay in most countries in obtaining ethical approval, members of the PRINTO are encouraged to recruit every available patient.

Quality of life project in the IAC project - 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 14 countries and 178 patients collected. The AC agrees on publishing a supplement on Clin Exp Rheumatol (similar to what published on J Clin Epidemiol 1998;51:1001-1203). On the supplement, with 80-100 pages, there will be: a) 1-2 introductory articles for general methodology b) 1 article **PER COUNTRY** with issues related to that specific translation plus the text of the translated CHAQ-CHQ. For editorial reason to be included in the supplement translations of the CHAQ-CHQ, for the countries who have not yet completed the task, should be handed in Pavia by the **END OF APRIL, 1999** and data collection for healthy children and children with JCA should be completed by March, 2000, and published by the end of 2000.

Cyclosporine project: The PRINTO and the Pediatric Rheumatology Collaborative Study Group (PRCSG) are conducting a Phase IV post-marketing surveillance study of cyclosporine-A (CyA) in patients with

polyarticular course IAC. A total of **60 patients** have been enrolled from 7 countries. 40 Euro will be paid for each patient collected, up to a maximum of 150 patients.

Meloxicam project: We have sent to some countries of the PRINTO group a feasibility survey for a trial sponsored by Boehringer to assess safety and efficacy of meloxicam. We have been recently informed that, based on a corporate decision this project will not be pursued any further at this time. 83 centres were contacted, with 54 (67%) responding to the feasibility survey.

European Pediatric Rheumatology Meeting (Glasgow, UK June 6-9, 1999): a PRINTO workshop will be held on Tuesday June 8, 1999. All the PRINTO members, and interested people, are invited to participate. The meeting of the national co-ordinators will be held at the end of the workshop to discuss current and future projects.

PRINTO on the Web: PRINTO is now on internet with more detailed information about the organisation, the list of members, and the on-going studies. If you want to join us you can connect at:

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