

PRINTO CURRENT PROJECTS

COUNTRIES	PRINTO MEMBERS/ CENTRES	MTX TRIAL no. of pts screened	Translations CHAQ/CHQ
Australia	1/1		
Austria	2/2		in progress
Belgium	4/3	in progress	done
Brazil	2/2		
Croatia	1/1		in progress
Czech Republic	7/5	4	done
Denmark	3/2		done
Finland	5/2	2	done
France	7/7	4	done
Germany	7/7	1	done
Greece	3/3		in progress
Hungary	1/1		done
Israel	3/3		done
Italy	24/12	31	done
Netherlands	3/3	8	done
Korea	1/1		in progress
Norway	7/3	5	done
Portugal	1/1		done
Russia	2/2		in progress
Slovakia	4/4	2	done
Spain	6/4	5	done
Sweden	2/2	in progress	done
Switzerland	2/2		in progress
Turkey	1/1		in progress
Un. Kingdom	7/5	12	done
Yugoslavia	1/1		in progress
Totals (25)	109/76	74	16
Sample size		~700	

“Pediatric Rheumatology International Trials Organisation”
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**AIR MAIL
PRINTS**

MAY 1999

“Pediatric Rheumatology International Trials Organisation”



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II NEWSLETTER

**European Pediatric Rheumatology Meeting
(Glasgow, UK June 6-9, 1999):**

a PRINTO workshop will be held on

Tuesday June 8, 1999 10.30-12.00 am

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)
- Pediatric Rheumatology Collaborative Study Group (PRCSG) projects update (D. Lovell)
- Meeting of the PRINTO national co-ordinators

Membership: We have now 109 effective members in 76 centres in 23 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). **36 centres** in **13 countries** have now obtained Ethics Committee approval. A total of **74 patients** have been enrolled in the screening phase with **6 patients** already randomised to higher dose of MTX.

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 **16 countries** and 230 patients collected. The Glasgow meeting (June 1999) will be the final deadline for completion of the translations of the CHAQ-CHQ for the countries who have not yet completed this task. Data collection for healthy children and children with JCA should 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. 40 Euro will be paid for each patient enrolled next September.

NEXT TRIAL SURVEY

Please return by mail or fax (+39-0382-502026)

INDICATE ONLY ONE TRIAL PER DISEASE

JUVENILE IDIOPATHIC ARTHRITIDES

SYSTEMIC LUPUS ERYTHEMATOSUS

DERMATOMYOSITIS

SYSTEMIC SCLEROSIS

LOCALISED SCLERODERMA

VASCULITIDES
