

PRINTO PROJECTS

COUNTRIES	No of pts enrolled MTX trial	No of pts enrolled JSLE study	No of pts enrolled JDM study
Argentina		9	7
Austria	2		2
Belgium	17	2	2
Brazil	49	15	7
Bulgaria	5	7	1
Chile		3	1
Costa Rica		4	3
Croatia			
Cuba			1
Czech Republic	18	3	4
Denmark		1	
Finland	9		1
France		3	2
Germany	12	10	8
Greece		1	2
Hungary			1
Georgia			
Israel	10	6	2
India		2	
Italy	174	16	12
Korea (South)	2		
Latvia			
Luxembourg			
Mexico	17	3	
Netherlands	42		2
Norway	19		
Portugal			2
Russia			
Slovakia	16		
Slovenia		1	
Spain	26	2	1
Sweden	6	1	
Switzerland	19	1	2
Turkey	16	6	1
Un. Kingdom	166		3
Yugoslavia		2	
USA	8		
Totals	633	98	67

"Paediatric Rheumatology International
 Trials Organisation - PRINTO"
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Paediatric Rheumatology International Trials Organisation - PRINTO



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VII NEWSLETTER

Dear Friends,

big changes have occurred in PRINTO since last time. PRINTO indeed moved to the Istituto G. Gaslini in Genova. The Gaslini hospital is the biggest pediatric hospital in Italy.

To fulfill the tasks related to the 3 projects financed by the European Union (see later for details) the PRINTO staff now include the following people:

Nicola Ruperto as trials coordinator

Anna Tortorelli, Monica Tufillo and Elisabetta Maggi as research assistant.

Luca Villa and Michele Pesce as web and data base designer.

Alberto Martini

NEW ADDRESS FOR PRINTO

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Membership: We have now 169 effective

members in 122 centres in 41 countries.
Methotrexate (MTX) trial (medium vs high dose) in the idiopathic arthritides of childhood (IAC): the goal of the trial was 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). A total of **633 patients** have been enrolled in the screening phase with **83** patients randomised to higher dose of MTX. The results of the trial will be presented at the PRES meeting in June in Stockholm, Sweden

Core sets of outcome measures and definition of improvement for juvenile systemic lupus erythematosus (JSLE) and juvenile dermatomyositis (JDM).

Aims of this new project is to establish:

1. a JSLE and JDM core sets of outcome measure for disease activity and disease damage assessment. This aim has already been reached through a consensus conference held in Pavia, Italy on April 2001.
2. prospective validation of the JSLE-JDM core sets with data collection among PRINTO members (see below).
3. JSLE and JDM definitions of

improvements to be used in future clinical trials.

The prospective validation of the JSLE-JDM core sets is on-going and 98 JSLE and 68 JDM patients have already been collected (see table next page).

Eligibility criteria: All patients in the active phase of the disease can be enrolled. Active phase is defined as follow:

- patients that have just started steroids or a new immunosuppressor
- patients that have just undergone a major change in the previous dosage of steroids or a immunosuppressor treatment

All new onset patients, or patients with disease relapse or flare for whom there is an important change in current therapy can be enrolled.

To allow PRINTO to keep track of all the patients enrolled in the study it will be greatly appreciated if you could send immediately the data by fax to Genova at

Fax +39-010-39-33-24 or +39-010-39-36-19

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 Genova, Italy.

A European information network on paediatric rheumatic diseases: Aims of this new project is to provide

- information on the pediatric rheumatic diseases for the families
 - a map of paediatric rheumatology centres
 - a map of associations to help families
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