



# PARC-ITP



EUROPEAN  
HEMATOLOGY  
ASSOCIATION



## Pediatric and Addult Intercontinental Registry of Chronic ITP (PARC-ITP)

### Intercontinental Childhood ITP Study Group (ICIS)

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### Summary

The PARC-ITP is a worldwide, multi-center registry designed to collect data prospectively of children and adults with newly diagnosed idiopathic thrombocytopenic purpura (ITP). Since chronic ITP of children and adults shows similarities, a common database is warranted to coordinate scientific activities in the field of ITP.

Clinical data, bleeding symptoms and management will be observed continuously by long-term follow-up over several years with the goal to recruit as many patients as possible.

The database will serve as the main part of the study with the potential to add subsequent side studies, which build the "trees in the park".

An amendment, dated May 11, 2005, to the study protocol proposes the anonymized collection of DNA from blood samples of PARC-ITP patients and 'healthy' controls in order to analyze genetic markers, i.e. genome wide single nucleotide polymorphisms (SNPs), and their correlation with data on demographics, severity, management and outcome collected in the current PARC-ITP database. The analyses will be coordinated by PARC-ITP. Foreseen institutions for analyses are NIH, Bethesda, Royal London and Basel.

All changes have been included in the PARC-ITP Study Protocol (Version 2.0, 2005-2-25) which can be downloaded at [www.unibas.ch/itpbasel](http://www.unibas.ch/itpbasel).

### Hypothesis

ITP is a heterogeneous disorder.

DNA polymorphisms may play a role in the pathogenesis or perpetuation of thrombocytopenia in chronic ITP. Specific single nucleotide polymorphisms (SNPs) may be useful markers of severity, chronicity, responses to therapy and overall disease outcome in patients with chronic ITP. SNPs studies may enhance our understanding of the cause and pathology of autoimmune disease and potentially may help identify new targets for therapeutic intervention.

### Aims of the study

#### Primary objectives:

- To establish a database on children and adults with ITP (demographics)
- To analyse the heterogeneity of ITP and to identify new patient selection criteria for future trials/side studies.

#### Secondary objectives:

- To study the natural history of ITP based on a long-term follow-up study
- To validate the diagnosis

Obtaining DNA profiles for 1'000 patients (children and adult) with ITP, and correlation analysis with demographic and clinical parameters of the PARC-ITP database.

### Eligibility

Children from the age of 2 months and adults with newly diagnosed ITP.

Informed consent and IRB approval is required before study entry.

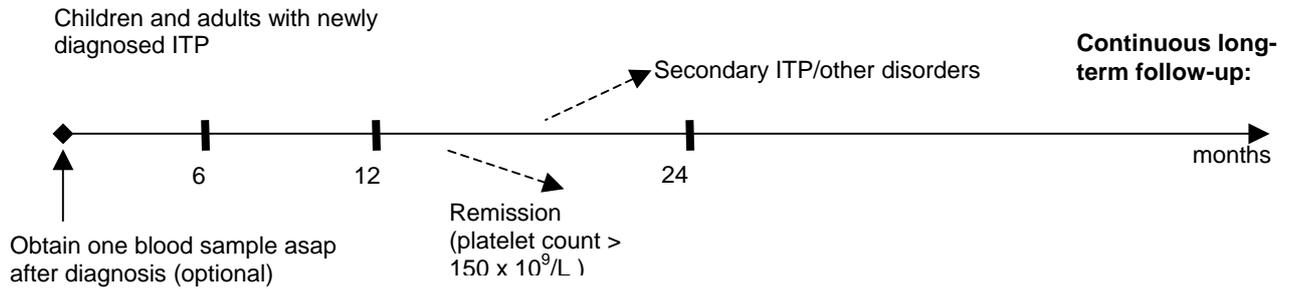
### Design

Worldwide cooperation of investigators willing to register patients anonymously.

Data collection by registry process, starting May 1, 2004.

**Blood sampling is optional and does not exclude from study participation.**

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### Questionnaires

For participation in the PARC-ITP registry: 2 page questionnaire, coordinated by ICIS central data office. Initial (= at time of initial diagnosis), at 6 months, 12months, and from then on yearly.

For optional collection of blood samples: 1 page questionnaire for 'healthy' controls, to be filled in by hand and included in the shipment.

**Registration and on-line patient data submission** at the password-protected site [www.parc-itp.net](http://www.parc-itp.net).

### Analysis and Publication

An interim analysis of demographic and clinical data will be performed when 1'000 eligible patients are enrolled or no later than 5 years. An interim analysis of genome wide SNPs will be performed when 500 blood samples from ITP patients have been collected or no later than 5 years. Investigators will be announced by accurate list on the website <http://www.unibas.ch/itpbasel> (see also ICIS Publication Policy).

### Funding

Shipping costs for blood samples are covered by ICIS.