

PATIENT INCLUSION – FIRST STEPS

A prospective outcome study on patients with profound combined immunodeficiency



You will find all essential documents for download at the website <http://www.pcid-study.org>
For download you need username and password. If you do not have any access, please contact:
p-cid@uniklinik-freiburg.de

Major inclusion criteria (definition see section 4.1, protocol, p. 26)

1. One major infection or one major immune dysregulation or one PID-associated malignancy
2. Two of four T cell criteria: low T cell counts, low naiv T cells, reduced proliferation, elevated γ/δ T cells
3. Age ≥ 1 and ≤ 16 years

How to include a patient – what steps to do at 1. Visit

1. Patient Consent (Information and Consent Form via download, see section 1.1)
 - print patient and parent information (appropriate for age) twice
 - let both copies of consent be dated and signed by parents/patient and investigator
 - give one signed copy to parents/patient, keep other form in study folder (see section 3.1)
2. Patient Eligibility Check (eligibility form via download, see section 1.2)
 - send completed form for eligibility check to
Fax: +49 (0)761 270-73770 or E-mail: p-cid@uniklinik-freiburg.de
 - in a few days you will receive an **eligibility confirmation form** and a study-specific **patient ID**. This ID should be noted in a list (patient identification log, section 2.1), on all forms, and will be used in all future correspondence on this patient. If you are sure that the inclusion criteria are fulfilled, do not wait for the patient ID to continue with the next steps.
3. Patient/parent QoL questionnaire s (age specific forms via download, see section 1.3)
 - let the questionnaires be completed by parents and child
 - fill in patient ID
 - send to Clinical Trials Unit by
fax: +49 (0)761 270-73770 or by E-mail: p-cid@uniklinik-freiburg.de or by regular mail (address labels see section 6.2)
4. Laboratory Analysis (if not performed within 6 months of study inclusion, details see section 4.2)
 - CBC with differential and platelets, CMV, EBV status
 - Immunoglobulins, Isohemagglutinin Titers, Vaccine Titers, sCD25
 - B cells, Memory B cells, NK cells, T cells, Naive T cells, g/d T cells, T cell proliferation,
 - Send dried Blood Filter Spot for TREC/KREC analysis (prepared from EDTA blood) to the study center laboratory by regular mail, no express delivery needed (manual and address labels s. sect. 8)
5. Study Forms (CRF) (via download see section 1.4), detailed guidance in CRF flowchart see section 6.1
 - complete, date and sign CRF **“P-CID visit 1”**
 - if patient undergoes primary HSCT, please also fill in CRF **“P – CID SCETIDE HSCT Initial Report Supplement”**
 - send completed CRF to Clinical Trials Unit by
fax: +49 (0)761 270-73770 or by E-mail: p-cid@uniklinik-freiburg.de or by regular mail (address labels see section 6.2)

You need further support? Please contact us

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