



PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title

Clinical and Laboratory Online Patient- and Research Registry for Primary Immunodeficiencies of the European Society for Immunodeficiencies (ESID)

Trial Acronym

ESID Registry

URL of the trial

<https://esid.org/Working-Parties/Registry-Working-Party/ESID-Registry>

Brief Summary in Lay Language

The Registry provides long term documentation of patients with primary (inborn) immunodeficiencies. These include e.g. common variable immunodeficiency (CVID) and severe combined immunodeficiency (SCID). The registry data makes it possible to determine the frequency of single diseases, as well as possible factors that may be related to the benefit of specific therapies.

Brief Summary in Scientific Language

The project aims to compile clinical and laboratory data of patients with primary immunodeficiencies (PID) in order to improve diagnosis, classification, prognosis and therapy. For this purpose, data is collected long-term, providing follow-up information for longitudinal analyses.

Organizational Data

- DRKS-ID: **DRKS00007776**
- Date of Registration in DRKS: **2015/02/05**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **493/14** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **D84 - Other immunodeficiencies**
- ICD10: **D80 - Immunodeficiency with predominantly antibody defects**
- ICD10: **D81 - Combined immunodeficiencies**
- ICD10: **D82 - Immunodeficiency associated with other major defects**
- ICD10: **D83 - Common variable immunodeficiency**

Interventions/Observational Groups

- Arm 1: **Baseline documentation: Age, sex, familial cases, first symptoms, diagnosis, haemtopoietic stem cell transplantation (HSCT), immunoglobulin replacement (Ig replacement), lab values, clinical features; Yearly follow-up: living status, therapy status (HSCT, Ig replacement), changes to diagnosis, lab values, clinical features**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Determine the epidemiology of primary immunodeficiencies (PID)

Secondary Outcome

Correlation of clinical features, life expectancy, complications, medication effects



Countries of recruitment

- DE **Germany**
- FR **France**
- UK **United Kingdom**
- CH **Switzerland**
- AT **Austria**
- PL **Poland**
- CZ **Czech Republic**
- SK **Slovakia**
- SI **Slovenia**
- HU **Hungary**
- ES **Spain**
- IT **Italy**
- EG **Egypt**
- IL **Israel**
- IR **Iran, Islamic Republic of**
- HR **Croatia**
- NL **Netherlands**
- BE **Belgium**
- IE **Ireland**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/12/11**
- Target Sample Size: **30000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

-



Gender: **Both, male and female**

- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Diagnosis of a primary immunodeficiency

Exclusion criteria

Diagnosis of a secondary immunodeficiency

Addresses

■ Primary Sponsor

**European Society for Immunodeficiencies (ESID)c/o Kenes Education B.V.
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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

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Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.