Assessment of Immunoglobulins (IgG) in a Long-term Non-interventional Study (SIGNS)

Purpose

This non-interventional, epidemiological study assesses long-term outcomes in subjects receiving immunoglobulins (IgG) for any treatment purpose, irrespective of the regimen prescribed by the treating physician, under routine clinical conditions among at least 550 subjects in Germany.

Long-term outcome data are collected on patient characteristics in the various indications, drug utilization of intravenous and subcutaneous IgG (e.g. treatment and dosing patterns), effectiveness (i.e. number of infections), tolerability, health related quality of life, and economic variables (number of hospitalizations, sick-leave days etc.) with the possibility to estimate direct costs.

Condition

- Primary Immunodeficiency (PID)
- Secondary Immunodeficiency (SID)
- Neurological Autoimmune Disease

Intervention

- Other: Immunoglobulin G (IgG)

Study Type: Observational [Patient Registry]
Study Design: Observational Model: Cohort
Time Perspective: Prospective
Target Follow-Up Duration: 2 Years

Official Title: An Open, Uncontrolled, Non-interventional Observational Cohort Outcome Study of Immunoglobulins in 3 Indications: Primary and Secondary Immunodeficiencies and Neurological Auto-immune Diseases

Resource links provided by NLM:
- MedlinePlus related topics: Autoimmune Diseases
- Drug Information available for: Immunoglobulin G

U.S. FDA Resources

Further study details as provided by Technische Universität Dresden:

Primary Outcome Measures:
- Immunoglobulin IgG dosage [ Time Frame: up to 54 months ] [ Designated as safety issue: No ]

  Dosage of immunoglobulins (IgG); frequency of IgG administrations; days of treatment with IgG; duration of infusion of IgG.

Secondary Outcome Measures:
- Infection rate [ Time Frame: up to 54 months ] [ Designated as safety issue: Yes ]

  For immunodeficiencies (primary PID and secondary SID): frequency of infections; degree of severity of infections (SBIs); duration of antibiotic treatment; necessity of antibiotic treatment.

- Neurological and muscular function (for neurological auto-immune diseases only) [ Time Frame: up to 54 months ] [ Designated as safety issue: No ]

  Grip strength (dynamometer) Electrophysiology (EMG, ENG); Inflammatory Neuropathy Cause and Treatment (INCAT) disability score; EDSS, annual relapse rate; Myasthenia Score.

- Duration of manifest auto-immune disease within the follow-up period (for neurological auto-immune diseases only). [ Time Frame: up to 54 months ] [ Designated as safety issue: No ]

- Health related quality of life [ Time Frame: up to 54 months ] [ Designated as safety issue: No ]

- Pharmacoeconomic parameters [ Time Frame: up to 54 months ] [ Designated as safety issue: No ]

  Number of sick-leave days Number of medical visits Days of hospitalisation due to infections or due to disability or loss of function Degree of disability

Estimated Enrollment: 704
Study Start Date: July 2010
Estimated Study Completion Date: April 2016
Estimated Primary Completion Date: December 2015 (Final data collection date for primary outcome measure)

Groups/Cohorts

<table>
<thead>
<tr>
<th>Patient treated with any IgG</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Other: Immunoglobulin G (IgG)</td>
</tr>
<tr>
<td>Any marketed SC or IV IgG can be documented</td>
<td>Not applicable. All interventions are at the discretion of the investigator. All marketed IgG formulations can be documented.</td>
</tr>
</tbody>
</table>

Detailed Description:

In view of the broad range of indications in immunodeficiency and immunomodulation, it is of interest to document the use of IgG under the conditions of everyday practice and to analyze the endpoints (outcomes). A prospective cohort study such as this is an important evidence source for such rare diseases as those mentioned above. The aim of this outcome study is to fill the gap of the lack of long-term data in these rare diseases treated with IgG.

Eligibility

<table>
<thead>
<tr>
<th>Genders Eligible for Study:</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accepts Healthy Volunteers:</td>
<td>No</td>
</tr>
<tr>
<td>Sampling Method:</td>
<td>Non-Probability Sample</td>
</tr>
<tr>
<td>Study Population</td>
<td></td>
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</tbody>
</table>

Disclaimer How to Read a Study Record
Ambulatory or hospital-based patients (no age restriction)

**Criteria**

**Inclusion Criteria:**
- Subjects of either gender with primary, severe secondary immunodeficiency and recurrent infections or neurological autoimmune diseases
- Naïve to IgG, or pre-treated with IgG
- Subject or parent/legally authorized representative has provided written informed consent.

**Exclusion Criteria:**
- None

**Contacts and Locations**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT01287689

**Contacts**

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**Locations**

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- **Klinik für Neurologie, Medizinische Hochschule**, Hannover, Germany
  - Contact: Martin Stangel, MD, PhD
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- **Klinik für Pädiatrische Rheumatologie, Allergologie und Neonatologie, Medizinische Hochschule (MHH)**, Hannover, Germany
  - Contact: Ulrich Baumann, MD, PhD
  - Principal Investigator: Ulrich Baumann, MD, PhD

- **Praxis für Hämatologie und Intensivmedizin**, Köln, Germany
  - Contact: Marcel Reiser, MD, PhD
  - Principal Investigator: Marcel Reiser, MD, PhD

- **Fachbereich Pädiatrische Rheumatologie, Immunologie und Infektologie am Klinikum St. Georg gGmbH Leipzig, Akademisches Lehrkrankenhaus der Universität**, Leipzig, Germany
  - Contact: Michael Borte, MD, PhD
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- **Mannheimer Onkologie-Praxis**, Mannheim, Germany
  - Contact: Manfred Hensel, MD, PhD
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**Sponsors and Collaborators**

- **Technische Universität Dresden**
- **GWT-TUD GmbH**

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- **Study Director:** Claudia Sommer, MD, PhD
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**More Information**

Additional Information:

- Related Info: [Learn About Clinical Studies](#)
- Publications:

- Responsible Party: Technische Universität Dresden
- ClinicalTrials.gov Identifier: NCT01287689
- Other Study ID Numbers: SIGNS
- Study First Received: January 24, 2011
- Last Updated: July 16, 2014
- Health Authority: Germany: Paul-Ehrlich Institut (PEI)
Keywords provided by Technische Universität Dresden:
Non-interventional trial
immunodeficiency
outcome study, registry
long-term outcomes, drug utilization
effectiveness, treatment patterns

Additionall relevant MeSH terms:
Autoimmune Diseases
Immunologic Deficiency Syndromes
Neoplasm-Metastasis
Imune System Diseases
Neoplasms
Neoplastic Processes
Pathologic Processes

ClinicalTrials.gov processed this record on December 07, 2014