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

This study is currently recruiting participants. (see Contacts and Locations)

Verified July 2014 by Technische Universität Dresden

Sponsor:
Technische Universität Dresden

Collaborator:
GWT-TUD GmbH

Information provided by (Responsible Party):
Technische Universität Dresden

ClinicalTrials.gov Identifier:
NCT01287689

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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	Intervention
Primary Immunodeficiency (PID) Secondary Immunodeficiency (SID) Neurological Autoimmune Disease	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	Assigned Interventions
Patient treated with any IgG Any marketed SC or IV IgG can be documented	Other: Immunoglobulin G (IgG) Not applicable. All interventions are at the discretion of the investigator. All marketed IgG formulations can be documented.

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

Genders Eligible for Study: Both
Accepts Healthy Volunteers: No
Sampling Method: Non-Probability Sample

Study Population

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

Contact: David Pittrow, MD, PhD. +49351458 ext 2815 david.pittrow@mailbox.tu-dresden.de

Locations

Germany

Klinik für Neurologie, St. Josefs-Hospital der Ruhr-Univ. Bochum, Germany Contact: Ralf Gold, MD, PhD Principal Investigator: Ralf Gold, MD, PhD	**Recruiting**
Institute for Clinical Pharmacology Dresden, Germany, D-01307 Contact: Wilhelm Kirch, MD, PhD +49351458 ext 2008 wilhelm.kirch@mailbox.dresden.de Principal Investigator: Wilhelm Kirch, MD, PhD	**Recruiting**
Klinik für Neurologie, Medizinische Hochschule Hannover, Germany Contact: Martin Stangel, MD, PhD Principal Investigator: Martin Stangel, MD, PhD	**Recruiting**
Klinik für Pädiatrische Pneumologie, Allergologie und Neonatologie, Medizinische Hochschule (MHH). Hannover, Germany Contact: Ulrich Baumann, MD, PhD Principal Investigator: Ulrich Baumann, MD, PhD	**Recruiting**
Praxis für Hämatologie und Internistische Onkologie Köln, Germany Contact: Marcel Reiser, MD, PhD Principal Investigator: Marcel Reiser, MD, PhD	**Recruiting**
Fachbereich Pädiatrische Rheumatologie, Immunologie und Infektiologie am Klinikum St. Georg gGmbH Leipzig, Akademisches Lehrkrankenhaus der Universität Leipzig, Germany Contact: Michael Borte, MD, PhD Principal Investigator: Michael Borte, MD, PhD Sub-Investigator: Maria Fasshauer, MD	**Recruiting**
Mannheimer Onkologie-Praxis Mannheim, Germany Contact: Manfred Hensel, MD, PhD Principal Investigator: Manfred Hensel, MD, PhD	**Recruiting**

Sponsors and Collaborators

Technische Universität Dresden

GWT-TUD GmbH

Investigators

Principal Investigator:	Wilhelm Kirch, MD, PhD	Institute for Clinical Pharmacology, Medical Faculty, Technical University Dresden, Germany
Study Chair:	David Pittrow, MD, PhD	Institute for Clinical Pharmacology, Medical Faculty, Technical University, Dresden, Germany
Study Director:	Michael Borte, MD, PhD	Fachbereich Pädiatrische Rheumatologie, Immunologie und Infektiologie am Klinikum St. Georg gGmbH Leipzig, Akademisches Lehrkrankenhaus der Universität Leipzig, Germ
Study Director:	Ulrich Baumann, MD, PhD	Klinik für Pädiatrische Pneumologie, Allergologie und Neonatologie, Medizinische Hochschule Hannover (MHH), Germany
Study Director:	Manfred Hensel, MD, PhD	Mannheimer Onkologie Praxis, Mannheim, Germany
Study Director:	Dörte Huscher	Epidemiologie, Rheumaforschungszentrum Berlin, Germany
Study Director:	Marcel Reiser, MD, PhD	PIOH - Praxis Internistische Onkologie, Hämatologie, Köln, Germany
Study Director:	Martin Stangel, MD, PhD	Klinik für Neurologie, Medizinische Hochschule Hannover (MHH), Germany
Study Director:	Ralph Gold, MD, PhD	Klinik für Neurologie, St. Josef-Hospital, Klinikum der Ruhr-Universität Bochum, Germany
Study Director:	Claudia Sommer, MD, PhD	Neurologische Klinik und Poliklinik, Universitätsklinik Würzburg, Germany

More Information

Additional Information:

Related Info

Publications:

Borte M, Baumann U, Pittrow D, Hensel M, Fasshauer M, Huscher D, Reiser M, Stangel M, Gold R, Kirch W; Liste der aktuell beitragenden Zentren, sortiert nach Postleitzahlen (mindestens ein Patient zum 1.3.2012). [Immunoglobulins in PID, SID and neurological autoimmune disease]. Dtsch Med Wochenschr. 2012 Mar;137(13):675-80. doi: 10.1055/s-0032-1304844. Epub 2012 Mar 20. Review. German.

Stangel M, Baumann U, Borte M, Fasshauer M, Hensel M, Huscher D, Kirch W, Pittrow D, Reiser M, Gold R. Treatment of neurological autoimmune diseases with immunoglobulins: first insights from the prospective SIGNS registry. J Clin Immunol. 2013 Jan;33 Suppl 1:S67-71. doi: 10.1007/s10875-012-9789-6. Epub 2012 Sep 14.

Kirch W, Gold R, Hensel M, Fasshauer M, Pittrow D, Huscher D, Reiser M, Stangel M, Baumann U, Borte M. [Assessment of immunoglobulins in a long-term non-interventional study (SIGNS Study). Rationale, design, and methods]. Med Klin (Munich). 2010 Sep;105(9):647-51. Epub 2010 Sep 28. German.

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Keywords provided by Technische Universität Dresden:
Non-interventional trial
immunodeficiency
outcome study, registry
long-term outcomes, drug utilization
effectiveness, treatment patterns
patient characteristics under real life conditions
factors for treatment success
long-term tolerability
quality of life

Additional relevant MeSH terms:
Autoimmune Diseases
Immunologic Deficiency Syndromes
Neoplasm Metastasis
Immune System Diseases
Neoplasms
Neoplastic Processes
Pathologic Processes
Antibodies
Immunoglobulin G
Immunoglobulins
Immunologic Factors
Pharmacologic Actions
Physiological Effects of Drugs

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