International GBS Outcome Study.

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The IGOS aims to identify clinical and biological determinants and predictors of disease course and outcome in individual patients with Guillain-Barré syndrome, as early as possible after onset of disease.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22932

Source
Nationaal Trial Register

Brief title
IGOS

Health condition

Guillain-Barré syndrome

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: GBS-CIDP Foundation International

Intervention

Outcome measures

Primary outcome

Primary clinical outcomes in IGOS are disability (GBS disability score and R-ODS), weakness (MRC sumscore), Limitations (ONLS), Fatigue (FSS) and quality of life (EuroQoL) during a follow-up of one year.

Secondary outcome

Secondary outcomes in IGOS are these same items at two and three year after diagnosis, and the complications caused by GBS.

Study description

Background summary

Definition:
International GBS Outcome Study (IGOS) is a study of the Inflammatory Neuropathy Consortium (INC) and Peripheral Nerve Society (PNS) on disease course and outcome in Guillain-Barré syndrome (GBS).

Study aim:
The IGOS aims to identify clinical and biological determinants and predictors of disease course and outcome in individual patients with GBS, as early as possible after onset of disease.

Study design:
A prospective observational international multi-centre study including at least 1000 patients with GBS and a follow-up period of at least one year.

Patients:
All patients with GBS and variants of GBS, including Miller Fisher syndrome (MFS) and overlap syndromes, within four weeks of onset of weakness can be included.

Methods:
Clinical information will be obtained via a web based data support according to a pre-defined protocol including eight visits: at entry, 1 week, 2 weeks, 4 weeks, 8 weeks, 13 weeks, 26 weeks and 52 weeks. Routine diagnostic electrophysiology data will be collected in the first week and if possible at 4 weeks. Serum samples will be obtained at all eight visits. DNA will be extracted from a single blood sample obtained in the first month. There is an option to participate in two additional research modules:
1. Collect cerebrospinal fluid (CSF) during routine diagnostic work-up for proteomic studies;
2. Extend the follow-up to two and three years. Additional studies may be added in the future.

Organisation:
Participation in IGOS is reserved for neurologists who are a member of the INC or participate in a region or country network lead by a member of the INC. Participants will own, share and use the data for research purposes only. IGOS will be supervised by a Steering Committee and Country and Region coordinators. Expertise Groups will focus on specific research areas, including:

1. Prognostic modelling: development of models to predict clinical course and outcome;
2. Treatment interventions: defining treatment practice, effects and side-effects; I-SID GBS study: compare the functional outcome between patients who have received a single dose of IVIg and those who have received a second dose of IVIg, according to the local treatment policy;
3. Pharmacokinetics of IVIg: defining serum IgG levels after IVIg in relation to outcome;
4. Electrophysiology: prognostic relevance of electrophysiological classification;
5. Preceding events: defining type of infections/vaccinations related to GBS and outcome;
6. Anti-neural antibodies: characterisation of serum antibodies related to GBS and outcome;
7. CSF biomarkers: proteomic studies of CSF in relation to GBS and outcome;
8. Genetic markers: genetic studies to define polymorphisms related to GBS and outcome;
9. Paediatric GBS: characterisation of clinical course and outcome in children with GBS;
10. Long-term outcome: residual disability and impact 2 and 3 years after disease onset;
11. Outcome measures: development of clinical outcome measures to monitor GBS.

Expected results:
IGOS will result in a large prospective, standardized clinical database and biobank from GBS patients. Expertise Groups will use these data to determine the processes of disease progression and recovery in GBS, to develop prognostic models, conduct selective therapeutic trials and personalize treatment.

Funding:
The GBS-CIDP Foundation International has funded the IGOS. Additional funding will be sought.

The probable participating countries are: The Netherlands, United Kingdom, USA, Belgium, France, Germany, Italy, Brazil, India, Singapore, Denmark, Australia, Canada.

Study objective

The IGOS aims to identify clinical and biological determinants and predictors of disease course and outcome in individual patients with Guillain-Barré syndrome, as early as possible after onset of disease.

Study design

Standard time points for evaluation of the clinical condition are at admission, and 1, 2, 4, 26, 52 weeks after admission. In addition, patients still admitted will also be evaluated at week 8 and 13 after admission. Week 104 and 156 are optional.

Intervention

IGOS is an observational studie, there are no interventions.

Contacts

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Eligibility criteria

Inclusion criteria

Criteria for inclusion of patients in the IGOS:
1. Fulfil the diagnostic criteria for GBS of the National Institute of Neurological Disorders and Stroke (NINDS). In addition all patients with Miller Fisher syndrome (MFS) and other variants of GBS, including overlap syndromes can be included, for which additional diagnostic criteria will be provided;
2. Inclusion of all males and females of all ages, independent of disease severity and treatment;
3. Inclusion within two weeks of onset of weakness;
4. Opportunity to conduct a follow-up of at least one year;
5. Informed consent of the patient or, in case of children, of the parents or legal guardians.

Criteria for inclusion of patients in the optional research modules of the IGOS:
1. Additional informed consent is required for each optional research module:
A. CSF biomarkers: additional volume obtained at diagnostic spinal tap;
B. Long-term outcome: additional clinical assessments at two and three years.

Exclusion criteria

To limit selection bias as much as possible there are no exclusion criteria to be included in IGOS.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2012
Enrollment:	1000
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-02-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47523
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3146
NTR-old	NTR3290
Other	METC Erasmus MC : MEC-2011-477
ISRCTN	ISRCTN wordt niet meer aangevraagd.
CCMO	NL38706.078.11
OMON	NL-OMON47523

Study results

Summary results
N/A