International Second Immunoglobulin Dose in Guillain-Barré Syndrome patients with poor prognosis.
NO LONGER A SEPARATE STUDY. THIS STUDY WILL BELONG TO THE IGOS STUDY (NTR 3290).

No registrations found.

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

Summary

ID

NL-OMON24041

Source
NTR

Brief title
I-SID GBS study

Health condition

Guillain-Barré syndrome

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Talecris Plasma Resources

Intervention

Outcome measures

Primary outcome

To determine whether a second IVIg course in GBS patients with a poor prognosis (mEGOS 6-12) improves functional outcome after 4 weeks.

Secondary outcome

To investigate whether a second IVIg course in GBS patients with a poor prognosis:

1. Improves functional outcome or muscle strength after 8, 12 and 26 weeks;

2. Lowers the percentage of patients requiring assisted ventilation, reduces the duration (number of days) on a ventilator or days in the intensive care unit;

3. Reduces the time (days) to hospital discharge;

4. Reduces the frequency of secondary deterioration due to treatment-related fluctuations (TRF);

5. Increases the frequency of treatment related complications;

6. Reduces GBS-related mortality;

7. Increases serum IgG further (and to what extent) and assess any relationship to IgG level after second IVIg dose and outcome.

To investigate whether:

1. Serum IgG increase after the first IVIg dose is lower in patients with a poor prognosis.

Study description

Background summary

Rationale:

Guillain-Barré syndrome (GBS) is the most frequent cause of acute neuromuscular weakness in the Western world. GBS patients have a variable prognosis; 20-30 percent needs mechanical ventilation, 20 percent are unable to walk after 6 months and 3-5 percent dies. Standard single IVIg dose treatment (0.4g/kg for 5 consecutive days) is a proven effective

treatment for GBS. Using a simple clinical scoring system, it is now possible to accurately predict which patients have a poor prognosis. Those GBS patients with a poor prognosis may benefit from a second dose of intravenous immunoglobulin (IVIg).

Objective:

To determine whether a second dose of IVIg in GBS patients with a poor prognosis improves functional outcome after 4 weeks. Secondary outcomes include functional outcome after 8, 12 and 26 weeks, duration of mechanical ventilation, length of hospital and ICU stay, frequency of treatment related fluctuations (TRF), mortality and change in blood IgG levels.

Study design:

A prospective, international, multicenter, observational study design will be used to study the effect of a second IVIg dose in patients with a poor prognosis. All GBS patients who will be treated with IVIg can be included in this study. Prognosis will be determined one week after start of treatment with a standard IVIg regimen using an accurate and validated prognostic model (mEGOS). Currently the policy of providing additional courses of IVIg in GBS patients with a poor prognosis varies among different centers. Prior to start of this I-SID study, all participating centers will be asked about their IVIg treatment policy in GBS patients with a poor prognosis based upon the mEGOS prognostic score. Investigators/physicians who treat patients with a poor prognosis (mEGOS 6-12) with a second IVIg dose/course, and treat relatively low risk patients (mEGOS 0-5) with a standard, single IVIg course will remain doing so in this I-SID GBS study. In contrast those who usually treat GBS patients only with a single IVIg course, irrespective of the mEGOS score will continue to do so. Thus, the treatment policy is at the discretion of individual participating investigators/physicians and in all cases, pre-defined treatment policy might be changed. Using this design, centers can participate and include GBS patients while not treating any patient with a poor prognosis with a second IVIg dose/course (and therefore will represent the control group); other centers who treat all patients with a poor prognosis with a second IVIg course will represent the treatment arm of this observational study.

Study population:

GBS patients 6 years and older, with an indication for IVIg treatment.

Main study parameters/endpoints:

The main study endpoint is functional outcome on the GBS disability scale 4 weeks after start

of the first IVIg dose. Other endpoints include functional outcome after 26 weeks.

Neurologists from the following countries that probably will participate are: The Netherlands, United Kingdom, USA, Belgium, France, Germany, Italy, Brazil, India, Singapore, Denmark, Australia, Canada.

The list of participating countries can change during the study.

Study objective

To determine whether a second dose of IVIg in GBS patients with a poor prognosis improves functional outcome after 4 weeks. Secondary outcomes include functional outcome after 8, 12 and 26 weeks, duration of mechanical ventilation, length of hospital and ICU stay, frequency of treatment related fluctuations (TRF), mortality and change in blood IgG levels.

Study design

Admission and 1, 2, 4, 8, 12 and 26 weeks after admission.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

To enter this GBS study:

1. Patients are diagnosed with GBS according to NINDS diagnostic criteria;

2. Indication to start IVIg treatment:

A. Patient is unable to walk unaided for >10 meter (grade 3, 4 or 5 of the GBS disability scale)
or;

B. There is otherwise an indication to start IVIg treatment according to the treating neurologist.

3. Onset of weakness due to GBS is less than 2 weeks ago;

4. Signed informed consent.

Exclusion criteria

To enter this GBS study:

1. Age less than 6 years;

2. Patient known to have a severe allergic reaction to properly matched blood products or plasma products;

3. Pregnancy or breastfeeding;

4. Patient known to have a selective IgA deficiency;

5. Patient shows clear clinical evidence of a polyneuropathy caused by e.g. diabetes mellitus (except mild sensory), alcoholism, severe vitamin deficiency, and porphyria;

6. Patient received immunosuppressive treatment (e.g. azathioprine, cyclosporine, mycofenolatemofetil, tacrolimus, sirolimus or > 20 mg prednisolon daily) during the last month;

7. Patient known to have a severe concurrent disease, like malignancy, severe cardiovascular disease, AIDS, severe COPD;

8. Inability to attend follow-up during 6 months.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-03-2012
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-02-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3130
NTR-old	NTR3281
Other	METC Erasmus MC : MEC-2011-401
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
The results of this I-SID GBS study will be submitted to an international journal.