

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).

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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...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24041

Bron

NTR

Verkorte titel

I-SID GBS study

Aandoening

Guillain-Barré syndrome

Ondersteuning

Primaire sponsor: Erasmus Medical Center

Overige ondersteuning: Talecris Plasma Resources

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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, mycophenolatemofetil, 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving tijdelijk gestopt
(Verwachte) startdatum: 01-03-2012
Aantal proefpersonen: 300
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 13-02-2012
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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