Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis, Study Two

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The purpose of this study is to establish the efficacy and safety of two different doses of alemtuzumab as a treatment for relapsing-remitting multiple sclerosis (MS), in comparison with Rebif® (interferon beta-1a). The study will enroll patients...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27332

Bron
NTR

Verkorte titel
CARE-MS II

Aandoening

Multiple Sclerosis, Relapsing-Remitting

Ondersteuning

Primaire sponsor: Genzyme Corporation
Overige ondersteuning: Genzyme Corporation
Bayer Schering Pharma AG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Time to Sustained Accumulation of Disability (SAD) [Time Frame: 2 years]

- Relapse Rate [Time Frame: 2 years]
(Rater-blinding of efficacy outcomes)

Toelichting onderzoek

Achtergrond van het onderzoek

The purpose of this study is to establish the efficacy and safety of two different doses of alemtuzumab as a treatment for relapsing-remitting multiple sclerosis (MS), in comparison with Rebif® (interferon beta-1a). The study will enroll patients who have received an adequate trial of disease-modifying therapies but continued to relapse while being treated, and who meet a minimum severity of disease as measured by MRI. Patients will have monthly laboratory tests and comprehensive testing every 3 months.

Every patient will receive active treatment; there is no placebo. The 24 mg alemtuzumab dose is closed to enrollment so newly enrolled patients will be randomly assigned to treatment with either 12 mg alemtuzumab or Rebif® at a 2:1 ratio (ie, 2 given 12 mg alemtuzumab for every 1 given Rebif®). Alemtuzumab will be administered in two annual cycles, once at the beginning of the study and again 1 year later. Rebif® will be self-injected 3 times per week for as long as the study continues. All patients will be required to return to their study site every 3 months for neurologic assessment. In addition, safety-related laboratory tests will be performed at least monthly. Participation in this study will end 2 years after the start of treatment for each patient. Additionally, all patients who receive alemtuzumab will be followed in an extension study for safety and efficacy assessments. Patients who receive Rebif® and complete 2 years on study may be eligible to receive alemtuzumab in an extension study.

Doel van het onderzoek

The purpose of this study is to establish the efficacy and safety of two different doses of alemtuzumab as a treatment for relapsing-remitting multiple sclerosis (MS), in comparison with Rebif® (interferon beta-1a). The study will enroll patients who have received an adequate trial of disease-modifying therapies but continued to relapse while being treated, and who meet a minimum severity of disease as measured by MRI. Patients will have monthly laboratory tests and comprehensive testing every 3 months.

Onderzoeksopzet

2 years

Onderzoeksproduct en/of interventie

Experimental intervention 1:
alemtuzumab: 12 mg per day administered through IV, once a day for 5 consecutive days at

Month 0 and 12 mg per day administered through IV, once a day for 3 consecutive days at Month 12

Experimental intervention 2:
alemtuzumab: 24 mg per day administered through IV, once a day for 5 consecutive days at Month 0 and 24 mg per day administered through IV, once a day for 3 consecutive days at Month 12 (Note: The 24 mg alemtuzumab dose is closed to enrollment.)

Active Comparator: interferon beta-1a (Rebif): 44 mcg administered 3-times weekly by SC injections for at least 2 years.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18 - 55 years old
2. Diagnosis of MS and MRI scan demonstrating white matter lesions attributable to MS
3. Onset of MS symptoms within 10 years
4. EDSS score 0.0 to 5.0
5. Greater than or equal to 2 MS attacks within 24 months, with greater than or equal to 1

attack within 12 months
6. Greater than or equal to 1 MS attack (relapse) during treatment with a beta interferon therapy or glatiramer acetate after being on that therapy for at least 6 months within 10 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous treatment with alemtuzumab
2. Previous treatment with any investigational drug (i.e. medication that is not approved at any dose or for any indication)
3. Treatment with natalizumab, methotrexate, azothioprine or cyclosporine in the past 6 months
4. Previous treatment with mitoxantrone, cyclophosphamide, cladribine, rituximab or any other immunosuppressive or cytotoxic therapy (other than steroid treatment)
5. Any progressive form of MS
6. Any progressive form of MS
7. Any disability acquired from trauma or another illness that could interfere with evaluation of disability due to MS
8. Major systemic disease that cannot be treated or adequately controlled by therapy
9. Active infection or high risk for infection
10. Autoimmune disorder (other than MS)
11. Impaired hepatic or renal function
12. History of malignancy, except basal skin cell carcinoma
13. Medical, psychiatric, cognitive, or other conditions that compromise the patient's ability to understand the patient information, to give informed consent, to comply with the trial protocol, or to complete the study
14. Of childbearing potential with a positive serum pregnancy test, pregnant, or lactating
15. Current participation in another clinical study or previous participation in CAMMS323
16. Previous hypersensitivity reaction to any immunoglobulin product
17. Known allergy or intolerance to interferon beta, human albumin, or mannitol
18. Intolerance of pulsed corticosteroids, especially a history of steroid psychosis
19. Inability to self-administer subcutaneous (SC) injections or receive SC injections from caregiver
20. Inability to undergo MRI with gadolinium administration
21. Unwilling to use a reliable and acceptable contraceptive method throughout the study period (fertile patients only).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-10-2007
Aantal proefpersonen:	700
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-09-2008
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	NL1409

Register	ID
NTR-old	NTR1469
Ander register	ClinicalTrials.gov NCT00548405 : CAMMS324
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

- Coles AJ, Cox A, Le Page E, et al. The window of therapeutic opportunity in multiple sclerosis: evidence from monoclonal antibody therapy. J Neurol. 2006;253(1);98-108.

- Fox E, Sullivan H, Gazda S. Open label, single-arm, Phase II study of alemtuzumab in patients with active relapsing-remitting multiple sclerosis who have failed licensed beta-interferon therapies. Poster presentation P06.07 at the 59th Annual Meeting of the American Academy of Neurology (AAN) on 03 May 2007

- CAMMS223 Trial Investigators; Coles AJ, Compston DA, Selmaj KW, Lake SL, Moran S, Margolin DH, Norris K, Tandon PK. Alemtuzumab vs. interferon beta-1a in early multiple sclerosis. N Engl J Med. 2008 Oct 23;359(17):1786-801.