ISRCTN68218781 https://doi.org/10.1186/ISRCTN68218781

A Multi-center, Double Blind, Randomized, Placebo Controlled, Parallel Group Trial Investigating Methylprednisolone in Combination with Interferon-beta-1a for the Treatment of Relapsing-Remitting Multiple Sclerosis

Submission date
31/03/2004

Registration date
01/04/2004

Last Edited
29/03/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mads Ravnborg

Contact details
Rigshospitalet
Department of Neurology, 2082
Blegdamsvej 9
Copenhagen
Denmark
DK-2100
+45 3545 8076
MADSRH03794RAVNBORG@rh.dk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00168766

Protocol serial number
MECOMBIN

Study information

Scientific Title

Acronym
MECOMBIN

Study objectives
Added as of 21/05/2008:
The primary objective of this study is to determine whether combination treatment (adding methylprednisolone to Avonex®) reduces progression of disability over 4 years compared to Avonex® alone. The study will also investigate whether combination therapy has any impact on the incidence of relapse and brain atrophy as measured by MRI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Multicentre, randomised, double-blind, placebo-controlled, parallel group trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Relapsing Remitting Multiple Sclerosis (MS)

Interventions
Interventions are standard interferon beta-1a therapy plus randomisation to either monthly oral methylprednisolone pulsed therapy (1.5 g/month) or matching placebo

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Methylprednisolone, Interferon-beta-1a

Primary outcome(s)
Added as of 21/05/2008:
To estimate the effect interferon-beta-1a in combination with methylprednisolone vs interferon-beta-1a in combination with placebo on the time to onset of disability progression sustained over at least 6 months based on change from randomisation in EDSS (Time Frame: 4 years)

Key secondary outcome(s)
Not provided at time of registration

Completion date
30/11/2008

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/05/2008:
1. Informed consent
2. Relapsing remitting MS according to Poser criteria or McDonell criteria and naïve to therapy
3. Extended Disability Status Scale (EDSS) score of 4.0 or less at baseline
4. Clinical activity as defined by at least one relapse in the last year

Previous inclusion criteria:
Adult subjects aged 18-55 with relapsing remitting MS, previously untreated with immunomodulatory drugs.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Key exclusion criteria
Exclusion criteria added as of 21/05/2008:
1. Relapse in the month prior to enrolment
2. Treatment with immunosuppressive drugs for MS
3. History of major depression
4. Former severe reactions to corticosteroids
5. Pregnant women

6. Diabetes mellitus, and drug or alcohol dependency
7. Known or suspected allergy to trial products

Date of first enrolment
01/01/2003

Date of final enrolment
30/11/2008

Locations

Countries of recruitment
United Kingdom

Belgium

Denmark

Finland

Netherlands

Norway

Sweden

Switzerland

Study participating centre
Rigshospitalet
Copenhagen
Denmark
DK-2100

Sponsor information

Organisation
Biogen Idec

ROR
https://ror.org/02jqkb192

Funder(s)

Funder type
Industry

Funder Name
Investigator led study, supported by funding from Biogen Idec.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2010		Yes	No