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	Recruitment status	[_] Prospectively registered
31/03/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/04/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/03/2012	Nervous System Diseases	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00168766

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

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

Age group
Adult

Lower age limit

18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
400

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
Belgium

Denmark

Finland

Netherlands

Norway

Sweden

Switzerland

United Kingdom

Study participating centre
Rigshospitalet
Copenhagen

Denmark
DK-2100

Sponsor information

Organisation
Biogen Idec

Sponsor details
Klaus Krasilnikoff MD
Biogen Idec
Lyngbyvej 28
Copenhagen
Denmark
DK-2100
+45 3916 9191
klaus.krasilnikoff@biogenidec.com

Sponsor type
Not defined

ROR
https://ror.org/02jqkb192

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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