

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/04/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/03/2012	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Study design

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

Primary study design

Interventional

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 McDonnell 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