

# 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

<b>Submission date</b> 31/03/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/04/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/03/2012	<b>Condition category</b> 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

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## 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 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

### 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**  
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**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?
<a href="#">Results article</a>	results	01/07/2010		Yes	No