# Dexamethason for the treatment of exacerbations in multiple sclerosis

Submission date	Recruitment status	Prospectively registered
22/11/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/11/2006	Completed	Results
Last Edited	Condition category	Individual participant data
23/09/2021	Nervous System Diseases	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

#### Protocol serial number

NL741 (NTR751)

# Study information

#### Scientific Title

Dexamethason for the treatment of exacerbations in multiple sclerosis

#### Acronym

dexamethason for relapse in MS

#### **Study objectives**

In this double-blind randomised controlled trial, we would like to show that a five-day treatment course with 16 mg/day oral dexamethason is effective in inducing recovery from an exacerbation of Multiple Sclerosis (MS).

# Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from the local medical ethics committee

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Multiple sclerosis (MS)

#### **Interventions**

Capsule containing 16 mg of dexamethason and identical placebo capsules will be prepared by the pharmacy of the Groningen University Medical Centre. The Medication (five capsules) will be given to the patient who will take one capsule per day for five days.

#### Intervention Type

Drug

#### **Phase**

Not Specified

# Drug/device/biological/vaccine name(s)

Dexamethason

# Primary outcome(s)

The number of patients who describe an improvement in their clinical status of at least five points on a ten point Likert scale (zero = unchanged, nine = complete recovery to the pre-exacerbation level) on day six.

# Key secondary outcome(s))

- 1. The number of patients needing additional intravenous methylprednisolon-treatment.
- 2. The number of patients who describe an improvement of at least five points on a ten-point-

Likert scale on day 14 and 28.

3. The number of patients with at least one point improvement on the Expanded Disability Status Scale (EDSS) on day six, 14, 28 compared to the EDSS-score at randomisation.

# Completion date

01/09/2007

# **Eligibility**

## Key inclusion criteria

- 1. Patients with MS, diagnosed according to the MacDonald criteria with a relapsing-remitting or secondary progressive subtype
- 2. Age older than 18 years, male or female
- 3. Patients have to be experiencing an exacrebation. Exacerbation is defined as the development of a new symptom or the worsening of an established symptom of MS of a duration of more than 24 hours and in the absence of fever or other disease
- 4. The exacerbation must encompass at least one of the following symptoms:
- a. arm or leg paresis
- b. gait problems because of paresis or ataxia
- c. limb ataxia
- d. sensory loss
- e. optic neurtitis
- f. diplopia
- 5. The exacerbation is present for no more than seven days at randomisation
- 6. Informed consent

# Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

#### Sex

**Not Specified** 

#### Key exclusion criteria

- 1. Use of corticosteroids in the previous three months
- 2. Contraindication for corticosteroid use (psychosis, active peptic ulcer, infection etc.)
- 3. Circumstanced in which constant medical monitoring is required (e.g. diabetes mellitus)
- 4. Pregnancy and breast-feeding
- 5. A MS-relapse in the previous eight weeks

#### Date of first enrolment

01/09/2006

# Date of final enrolment

01/09/2007

# Locations

## Countries of recruitment

Netherlands

Study participating centre
University Medical Centre Groningen (UCMG)
Groningen
Netherlands
9713 GZ

# Sponsor information

#### Organisation

University Medical Center Groningen (UMCG) (The Netherlands)

#### **ROR**

https://ror.org/03cv38k47

# Funder(s)

# Funder type

Not defined

#### **Funder Name**

Not provided at time of registration

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration