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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

- 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.

Overall study start date

01/09/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Target number of participants

60

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)

Sponsor details

P.O. Box 30001 Groningen Netherlands 9700 RB

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/03cv38k47

Funder(s)

Funder type Not defined

Funder Name

Not provided at time of registration

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration