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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

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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

Not Specified

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
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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 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