Dexamethason for the treatment of exacerbations in multiple sclerosis.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22907

Source
NTR

Brief title
dexamethason for relapse in MS

Health condition

multiple sclerosis

Sponsors and support

Primary sponsor: University Medical Centre Groningen
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The number of patients who describe an improvement in their clinical status of at least 5 points on a 10 point Likert scale (0=unchanged, 9=complete recovery to the pre-exacerbation level) on day six.

Secondary outcome

1. The number of patients needing additional intravenous methylprednisolon-treatment;

2. The number of patients who describe an improvement of at least 5 points on a 10-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 6, 14, 28 compared to the EDSS-score at randomisation.

Study description

Background summary

N/A

Study objective

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

Study design

N/A

Intervention

Capsule containing 16mg of dexamethason and identical placebo capsules will be prepared by the pharmacy of the Groningen University Medical Centre.
The Medication (5 capsules) will be given to the patient who will take one capsule per day for five days.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with multiple sclerosis (MS), diagnosed according to the MacDonald criteria with a relapsing-remitting or secundary progressieve subtype;

2. Age older than 18 yrs, 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 symptoms 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: arm or leg paresis, gait problems because of paresis or ataxia, limb ataxia, sensory loss, optic neurtitis, diplopia;

5. The exacerbation is present for no more than seven days at randomisation;

6. Informed consent.

Exclusion criteria

1. Use of corticosteroids in the previous three months;

2. Contraindication for coritcosteroid-use (psychosis, active peptic ulcer, infection etc.);

3. Circumstanced in which constant medical monitoring is required (e.g. diabetes mellitus);

4. Pregancy and breast-feeding;

5. A MS-relapse in the previous eight weeks.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-09-2006
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-08-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL741
NTR-old	NTR751
Other	: N/A
ISRCTN	ISRCTN40435212

Study results

Summary results
N/A