Dexamethason for the treatment of exacerbations in multiple sclerosis.

Gepubliceerd: 14-08-2006 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22907

Bron
NTR

Verkorte titel
dexamethason for relapse in MS

Aandoening

multiple sclerosis

Ondersteuning

Primaire sponsor: University Medical Centre Groningen
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-09-2006
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-08-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A