Verbanden tussen therapietrouw aan glatirameer acetaat (Copaxone) en ontvangen zorg bij patienten met aanvalsgewijze multipele sclerose.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26562

Source
NTR

Brief title
CAIR

Health condition

Multiple sclerosis, adherence, compliance, glatiramer acetate

Sponsors and support

Primary sponsor: MS4 Research Institute,
Ubbergseweg 34,
6522 KJ Nijmegen,
the Netherlands
Source(s) of monetary or material Support: Unrestricted grant from Teva Pharma Netherlands BV, Busweg 1, 2003 RN Haarlem and sanofi aventis Netherlands BV, Kampenringweg 45 D-E, 2803 PE Gouda

Intervention

Outcome measures

Primary outcome

Primary outcomes are correlations between:
1. Numbers of missed doses's;

2. Numbers of patients who discontinued GA treatment;

3. Numbers of care sessions's;

4. Duration of care per modality.

Secondary outcome

Secondary outcomes are (cor)relations between:
1. Number of missed doses's;

2. Numbers of patients who discontinued GA treatment;

3. Presence's;

4. Degree of socio-economic, health care, caregivers, disease, treatment and patient characteristics.

Study description

Background summary

RRMS patients treated with injectable immunomodulating drugs miss up to 30% of doses, and 17% of patients may discontinue treatment in the first 12 months. Treatment adherence is influenced by factors relating to socio-economic situation, health care and caregivers, disease, treatment and patient characteristics. Only few studies dealt with factors relating to adherence in GA-treated patients. Detailed knowledge on those modalities or durations of care given to GA-treated patients that significantly relate to adequate adherence could enable adherence-improving measures to be taken. Moreover, identification of patients at high risk of inadequate adherence could lead to even more effective care and more efficient allocation of limited resources.

The CAIR study is an investigator-initiated, prospective, web-based, patient-centred, nation-wide cohort study in the Netherlands.

Primary objective is to investigate whether adherence to GA treatment is associated with specific modalities or duration of received care. Secondary objective is to investigate whether

adherence to GA treatment is associated with aspects of socio-economic situation, health care and caregivers, disease (e.g. disease activity), treatment (e.g. adverse events) or patient characteristics (e.g. self-efficacy, health-related quality of life [HR-QoL], mood).

All data are acquired via the internet using a study website www.cairstudie.nl. All RRMS patients in the Netherlands who have decided to start GA treatment are eligible and are informed on the study by neurologists and nurses. Information is also available on websites from national MS patient organisations.

Number of missed doses per patient and number of patients having discontinued GA treatment are measures of adherence. Per care modality number of sessions and total care duration are measures of received care. The full spectrum of MS-relevant non-experimental care modalities that are available in the Netherlands are assessed. Care includes ‘physical’ contacts, e.g. in out-patient clinics, contacts by telephone, e-mail or internet, health-promoting activities or community care activities. Received care over the preceding 14 days is assessed by patients at baseline and every other week thereafter up to week month 12. Every 3 months neurologists and nurses record care modalities to which patients have been referred by them.
The Dutch Adherence Questionnaire-90 (DAQ-90) is a 90-item questionnaire based on the World Health Organisation (WHO) 2003 report on adherence and designed to comprehensively assess five domains of evidence-based determinants of adherence: socio-economic, health care and caregivers, disease, treatment, and patient-related factors. Self-efficacy is assessed by the MS Self-Efficacy Scale (MSSES). HR-QoL and mood are assessed by the Multiple Sclerosis Quality of Life-54 questionnaire (MSQoL-54). Relapses and adverse events that are probably or definitively related GA treatment are reported as well.

Study objective

Missing doses and early discontinuation are two levels of inadequate drug adherence. Multidisciplinary interventions may improve adherence. We hypothesize that in patients with multiple sclerosis (MS) certain modalities or durations of care are associated with adequate adherence to immunomoduating treatment, notably glatiramer acetate (GA). If so, knowledge on relations between care and adherence enables care givers to focus on specific care activities. Thus, increased adherence could make treatment more effective.

Study design

Care includes ‘physical’ contacts, e.g. in out-patient clinics, contacts by telephone, e-mail or internet, health-promoting activities or community care activities. Received care over the preceding 14 days is assessed by patients at baseline and every other week thereafter up to week month 12. Every 3 months neurologists and nurses record care modalities to which patients have been referred by them.
The Dutch Adherence Questionnaire-90 (DAQ-90) is a 90-item questionnaire based on the World Health Organisation (WHO) 2003 report on adherence and comprehensively assesses evidence-based determinants of adherence: socio-economic, health care and caregivers, disease, treatment, and patient-related factors; assessment at baseline. Self-efficacy is

assessed by the MS Self-Efficacy Scale (MSSES); asessment at baseline and month 12. HR-QoL and mood are assessed by the Multiple Sclerosis Quality of Life-54 questionnaire (MSQoL-54); assessmet at baseline and months 6 and 12. Relapses and adverse events that are probably or definitively related GA treatment are reported at months 3, 6, 9 and 12. Assessment of disability at baseline and month 12 with the Expanded Disability Status Scale (EDSS) is optional.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Indication for GA treatment in Relapsing Remitting MS (RRMS), as formulated by the regulatory authorities in the Netherlands;

2. Being relapse free and having stable symptoms for at least 30 days;

3. Willing and able to comply with the protocol for the duration of the study;

4. Having given written informed consent prior to any study-related procedure not part of standard neurological practice, with the understanding that the consent may be withdrawn by the patient at any time without prejudice to his/her neurological care.

Exclusion criteria

1. Contra-indications for GA as defined in the Summary of Product Characteristics text;

2. Hypersensitivity to glatiramer acetate or mannitol;

3. Worsening of symptoms suggestive of relapse;

4. Pregnancy or lactation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-07-2010
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	NL2326
NTR-old	NTR2432
Other	Independend Review Board Amsterdam : IRB 09.0429
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A