The effect of Acclydine on fatigue and functional status in patients with chronic fatigue syndrome.

Gepubliceerd: 01-09-2005 Laatst bijgewerkt: 13-12-2022

Acclydine is a plant sourced alkaloid which has effects on protein structure and metabolism. In particular it leads to the activation of the pituitary to increase release of growth hormone. The GH axis has been shown to be disturbed in CFS, so this...

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

Samenvatting

ID

NL-OMON21358

Bron
NTR

Verkorte titel
N/A

Aandoening

Chronic fatigue syndrome.

Ondersteuning

Primaire sponsor: University Medical Centre Nijmegen
The Netherlands.
Overige ondersteuning: Optipharma BV
Handelsweg 5
6114 BR Susteren
The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Fatigue-severity measured with CIS-fatigue;

2. Functional impairment measured with Sickness Impact Profile;

3. CDC-symptoms.

Toelichting onderzoek

Achtergrond van het onderzoek

Acclydine is a plant sourced alkaloid which has effects on protein structure and metabolism. In particular it leads to the activation of the pituitary to increase release of growth hormone. The GH axis has been shown to be disturbed in CFS, so this alkaloid could be of benefit in CFS.

During a 14-weeks placebo-controlled trial, the efficacy of Acclydine combined with amino-acids will be assessed in CDC-diagnosed CFS-patients.

Doel van het onderzoek

Acclydine is a plant sourced alkaloid which has effects on protein structure and metabolism. In particular it leads to the activation of the pituitary to increase release of growth hormone. The GH axis has been shown to be disturbed in CFS, so this alkaloid could be of benefit in CFS.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

14 weeks Acclydine combined with amino-acids.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. CDC-diagnosed CFS-patients
Male and female patients 18-65 years;

2. Elevated IGF-BP3/IGF-1 ratio;

3. High-fatigue severity level;

4. Substantial functional impairment;

5. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. Lactating women;

3. Participation in CVS treatment programs;

4. Recent participation in other CVS treatment research;

5. Psychiatric co-morbidity.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	22-10-2002
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	01-09-2005
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	NL133
NTR-old	NTR167
Ander register	: N/A
ISRCTN	ISRCTN77271661

Resultaten

Samenvatting resultaten
PLoS Clin Trials. 2007 May 18;2(5):e19.