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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21358

Source
NTR

Brief title
N/A

Health condition

Chronic fatigue syndrome.

Sponsors and support

Primary sponsor: University Medical Centre Nijmegen
The Netherlands.
Source(s) of monetary or material Support: Optipharma BV
Handelsweg 5
6114 BR Susteren
The Netherlands

Intervention

Outcome measures

Primary outcome

1. Fatigue-severity measured with CIS-fatigue;

2. Functional impairment measured with Sickness Impact Profile;

3. CDC-symptoms.

Secondary outcome

1. Activity level measured with actometer;

2. IGF-BP3-IGF-1 ratio.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

14 weeks Acclydine combined with amino-acids.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Pregnancy;

2. Lactating women;

3. Participation in CVS treatment programs;

4. Recent participation in other CVS treatment research;

5. Psychiatric co-morbidity.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2002
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	01-09-2005
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	NL133
NTR-old	NTR167
Other	: N/A
ISRCTN	ISRCTN77271661

Study results

Summary results
PLoS Clin Trials. 2007 May 18;2(5):e19.