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

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
13/05/2009

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR167

Study information

Scientific Title

Study objectives
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 chronic fatigue syndrome (CFS), so this alkaloid could be of benefit in CFS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committees

Study design
Randomised double blind placebo-controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic fatigue syndrome

Interventions
14 weeks acclydine combined with amino-acids.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Acclydine

Primary outcome measure
1. Fatigue-severity measured with CIS-fatigue
2. Functional impairment measured with Sickness Impact Profile
3. CDC-symptoms

Secondary outcome measures
1. Activity level measured with actometer
2. IGF-BP3-IGF-1 ratio

Overall study start date
22/10/2002

Completion date
01/10/2005

Eligibility

Key inclusion criteria
1. Centre of Diseases Control (CDC)-diagnosed CFS-patients
2. Male and female patients aged 18 - 65 years
3. Elevated IGF-BP3/IGF-1 ratio
4. High-fatigue severity level
5. Substantial functional impairment
6. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key 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

Date of first enrolment

22/10/2002

Date of final enrolment
01/10/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center St. Radboud
Nijmegen
Netherlands
6500 HB

Sponsor information

Organisation
University Medical Centre Nijmegen (Netherlands)

Sponsor details
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info@ozi.umcn.nl

Sponsor type
Hospital/treatment centre

Website
http://www.umcn.nl/homepage

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Industry

Funder Name
Optipharma BV (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/05/2007		Yes	No