

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

Submission date
20/12/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
20/12/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
13/05/2009

Condition category
Nervous System Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double blind placebo-controlled parallel group trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/05wg1m734>

Funder(s)

Funder type

Industry

Funder Name

Optipharma BV (Netherlands)

Results and Publications

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