The effect of ondansetron, a 5-Ht3 receptor antagonist, on fatigue severity and functional impairment in CFS-patients.

No registrations found.

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

Summary

ID

NL-OMON23597

Source
Nationaal Trial Register

Brief title
N/A

Intervention

Outcome measures

Primary outcome

1. Fatigue severity: measured with Checklist Individual Strenght;

2. Functional impairment: measured with Sickness Impact Profile;

. CDC-symptoms.

Secondary outcome

Fysical activity level: measured with actometer.

Study description

Background summary

Accumulating data in the literature support an important role for serotonin, in the neurobiology of CFS. Neuroendocrin and neuropharmacological studies point to an up-regulated or hyperresponsive serotonin system.

In a RCT by our own research group the SSRI fluoxetine proved to be ineffective in CDC-diagnosed CFS patients.

Positive reports of the use of serotonine inhibitors in the treatment of fatigue, due to hepatitis and to fibromyalgia, support an effect. Based on these findings we hypothesise that a serotonin antagonist could be effective in the treatment of CFS.

Study objective

Accumulating data in the literature support an important role for serotonin, in the neurobiology of CFS. Neuroendocrin and neuropharmacological studies point to an up-regulated or hyperresponsive serotonin system.

Positive reports of the use of serotonine inhibitors in the treatment of fatigue, due to hepatitis and to fibromyalgia, support an effect. Based on these findings we hypothesise that a serotonin antagonist could be effective in the treatment of CFS.

Study design

N/A

Intervention

10 weeks ondansetron.

Contacts

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Eligibility criteria

Inclusion criteria

1. CDC-diagnosed CFS-patients;

2. Male and female patients 18-65 years of age;

3. High-fatigue severity level;

4. Substantial functional impairment;

5. Written informed consent.

Exclusion criteria

1. Pregancy;

2. Lactating women;

3. Participation in CFS-treatment programs;

4. Participation in other CFS-research;

5. Psychopharmaca.

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):	19-06-2002
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	31-08-2005
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	NL172

Register	ID
NTR-old	NTR209
Other	: N/A
ISRCTN	ISRCTN02536681

Study results

Summary results
N/A