

The effect of ondansetron, a 5-Ht3 receptor antagonist, on fatigue severity and functional impairment in Chronic Fatigue Syndrome patients

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
15/06/2010

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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Contact details

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Additional identifiers

Protocol serial number

NTR209

Study information

Scientific Title

Study objectives

Accumulating data in the literature support an important role for serotonin, in the neurobiology of Chronic Fatigue Syndrome (CFS). Neuroendocrine and neuropharmacological studies point to an up-regulated or hyper-responsive serotonin system.

In a randomised controlled trial by our own research group the Selective Serotonin Reuptake Inhibitor (SSRI) fluoxetine proved to be ineffective in Centre for Diseases Control (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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised placebo controlled, parallel group, double blinded trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic fatigue syndrome

Interventions

10 weeks ondansetron versus placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ondansetron

Primary outcome(s)

1. Fatigue severity: measured with Checklist Individual Strength
2. Functional impairment: measured with Sickness Impact Profile
3. CDC-symptoms

Key secondary outcome(s)

Physical activity level: measured with actometer

Completion date

01/03/2006

Eligibility

Key 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

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 CFS-treatment programs
4. Participation in other CFS-research
5. Psychopharmaca

Date of first enrolment

19/06/2002

Date of final enrolment

01/03/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Department Internal Medicine - 541

Nijmegen

Netherlands

6500 HB

Sponsor information

Organisation

University Medical Centre Nijmegen (Netherlands)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

GlaxoSmithKline (Netherlands)

Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2010		Yes	No