ISRCTN02536681 https://doi.org/10.1186/ISRCTN02536681

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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
15/06/2010

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

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

Study design
Randomised placebo controlled, parallel group, double blinded trial

Primary study design
Interventional

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