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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
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
NTR209

Study information

Scientific Title

Study hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Condition
Chronic fatigue syndrome

Interventions

10 weeks ondansetron versus placebo.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ondansetron

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

Secondary outcome measures
Physical activity level: measured with actometer

Overall study start date
19/06/2002

Overall study end date
01/03/2006

Eligibility

Participant 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Participant exclusion criteria

1. Pregnancy
2. Lactating women
3. Participation in CFS-treatment programs
4. Participation in other CFS-research
5. Psychopharmaca

Recruitment start date
19/06/2002

Recruitment end date
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)

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (Netherlands)

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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	01/05/2010		Yes	No