

# 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

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

### **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 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

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

60

**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)

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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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/05/2010   |            | Yes            | No              |