

A comparison of high cocoa solid with absent cocoa solid chocolate in patients with chronic fatigue syndrome in a double blind randomised controlled trial

Submission date 05/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/01/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/05/2011	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Study information

Scientific Title

Study objectives

High polyphenol chocolate improves symptoms of Chronic Fatigue Syndrome (CFS)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Hull and East Riding Research Ethics committee on 06/10/2003 (ref: LREC/07/03/121)

Study design

Double blind randomised 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

Double blind cross over study using chocolate containing high polyphenols with low polyphenol chocolate with two weeks washout, eight weeks of initial intervention and eight weeks of cross-over intervention.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

High polyphenol chocolate

Primary outcome measure

Improvement of fatigue using Chandler Fatigue scale, London Handicap Scale and Hospital Anxiety and Depression Scale.

Secondary outcome measures

Change in weight

Overall study start date

01/10/2005

Completion date

01/10/2006

Eligibility**Key inclusion criteria**

1. Age group 18 to 35
2. Diagnosis of CFS as defined by the Centers for Disease Control (CDC) criteria
3. Severity of fatigue - a score of at least ten (out of 11) on the Chalder-Fatigue Scale (binary scored)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

10

Key exclusion criteria

1. Benzodiazepine use in the previous two months
2. Unwilling to give written, informed consent
3. Unable to complete study questionnaires

Date of first enrolment

01/10/2005

Date of final enrolment

01/10/2006

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
Micheal White Diabetes Centre
Hull
United Kingdom
HU3 2RZ

Sponsor information

Organisation
Hull and East Yorkshire Hospital NHS Trust (UK)

Sponsor details
c/o Mrs Nina Dunham
Research and Development Department
Castle Hill Hospital
Hull
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

Website
<http://www.hey.nhs.uk/>

ROR
<https://ror.org/01b11x021>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Research and Development Department, Hull Royal Infirmary (UK)

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	22/11/2010		Yes	No