

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

☐ Prospectively registered

☐ Protocol

Registration date
26/01/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
03/05/2011

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

ELSY No 2870

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)

Primary study design

Interventional

Study design

Double blind randomised trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Change in weight

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

Micheal White Diabetes Centre

Hull

United Kingdom

HU3 2RZ

Sponsor information

Organisation

Hull and East Yorkshire Hospital NHS Trust (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**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