ISRCTN03090939 https://doi.org/10.1186/ISRCTN03090939

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

Registration date
26/01/2007

Overall study status
Completed

Last Edited
03/05/2011

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

Contact name
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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)

Study design
Double blind randomised trial

Primary study design
Interventional

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. Unwillilng 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