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	Recruitment status	[ ] Prospectively registered
05/01/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/05/2011	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Stephen Atkin

Contact details
Micheal White Diabetes Centre
Hull Royal Infirmary
Analby Road
Hull
United Kingdom
HU3 2RZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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. 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

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