ISRCTN25655161 https://doi.org/10.1186/ISRCTN25655161

Effect of chocolate with and without polyphenols on health in type 2 diabetes

Submission date	Recruitment status
03/09/2009	No longer recruiting
Registration date	**Overall study status**
22/09/2009	Completed
Last Edited	**Condition category**
03/08/2012	Nutritional, Metabolic, Endocrine

[_] 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
Prof Stephen Atkin

Contact details
Brocklehurst Building
220-232 Anlaby Road
Hull
United Kingdom
HU3 2RW

Additional identifiers

Protocol serial number
1.1

Study information

Scientific Title
Crossover randomised controlled trial studying the effects of chocolate with and without polyphenols in type 2 diabetes

Acronym
ChocDM1

Study objectives
Eating high polyphenol chocolate can reduce cardiovascular risk in type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Riding Local Research Ethics Committee, approved on 21/11/2006 (ref: 06/Q1104 /128)

Primary study design
Interventional

Study design
Randomised cross-over trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Subjects were given either 45 g per day of high polyphenol chocolate or low polyphenol chocolate for 2 months. Following 1 month washout they were switched to the other chocolate.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Chocolate

Primary outcome(s)
Lipid profile

All outcome measures were measured at baseline, 8 weeks (following intervention 1), 12 weeks (following washout) and 20 weeks (following intervention 2).

Key secondary outcome(s)
Homeostatic Model Assessment (HOMA) index

All outcome measures were measured at baseline, 8 weeks (following intervention 1), 12 weeks (following washout) and 20 weeks (following intervention 2).

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Both males and females, ages 18 and above
2. Type 2 diabetes
3. Stable medication

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Changes in medication over the past 3 months

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Brocklehurst Building
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hull and East Yorkshire Hospitals Diabetes Charitable funds (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	01/11/2010		Yes	No