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

Submission date	Recruitment status	Prospectively registered	
03/09/2009	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
22/09/2009	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
03/08/2012	Nutritional, Metabolic, Endocrine		

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

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)

Study design

Randomised cross-over trial

Primary study design

Interventional

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