

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

Submission date 03/09/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/09/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/08/2012	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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)

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