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

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Not Specified

Participant information sheet

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 measure

Lipid profile

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

Secondary outcome measures
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).

Overall study start date
01/01/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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
England

United Kingdom

Study participating centre
Brocklehurst Building
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
c/o James Illingworth
Castle Hill Hospital
Daisy Building
Castle Road
Cottingham
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
Hull and East Yorkshire Hospitals Diabetes Charitable funds (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	01/11/2010		Yes	No