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# Short term effects of high polyphenol content chocolate on blood vessel health

| 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 |
| 15/08/2013 | Nutritional, Metabolic, Endocrine | |

## Plain English summary of protocol

Background and study aims
Dark chocolate rich in polyphenols (mainly epicatechin, a bitter compound) can reduce the risk of heart disease. The earliest signs of heart disease are thought to be linked to a reduction in the ability of the blood vessels to expand and deal with increased blood flow. This is called endothelial dysfunction. It is known that people with type 2 diabetes have increased levels of endothelial dysfunction and this could be part of their increased risk of developing heart disease. It is also thought that high blood glucose (sugar) may increase endothelial dysfunction. Experimental work with chocolate containing epicatechins suggests that this can reduce the level of endothelial dysfunction. Therefore, the aim of this study was to investigate if providing chocolate rich in polyphenols before a glucose drink would reduce the level of endothelial dysfunction when compared to a low polyphenol chocolate and water.

Who can participate?
Men and women (postmenopausal) aged between 40-75 years with type 2 diabetes.

What does the study involve?
The study involves a screening visit, which following giving informed consent will require blood samples to be taken to assess level of diabetes control (HbA1c), cholesterol (lipid profile) and kidney and liver function. These will assess that you are healthy enough to participate in the study. You will also have your blood pressure, height and weight measured.
A week after this, if all the screening tests are satisfactory, you will be invited back for a 3-hour test. This will require you to fast from midnight the previous evening. Initially you will have your endothelial function measured using an EndoPAT 2000, which involves having balloon inflating probes on the index finger of each hand and a blood pressure cuff on one arm. After five minutes rest, the blood pressure cuff will be inflated so that it stops the blood flow to your hand for five minutes. This is safe but might be uncomfortable. The cuff is then released to allow the blood flow to return to your hand. The change in flow will be used to calculate endothelial function/ dysfunction. You will then have a tube (cannula) placed in your arm and blood will be taken for testing for glucose, insulin and markers of endothelial function. At this point for the first visit you will be given water. One hour later the tests will be repeated and you will be given the glucose drink. The final series of tests will be repeated two hours after drinking the glucose drink.

You will be asked to return a week later where you will be given either a high polyphenol chocolate or a control chocolate with water one hour before the glucose test as described above. The following week you will be asked to return to eat the other chocolate before the testing is repeated for the third time.
In addition to the blood tests and the EndoPAT, you will be asked to keep a food and activity diary for the day before, the day of the testing and the day after and collect all your urine for the day before and day of the test. The diaries are to check if your lifestyle varies between the test days, and the urine will indicate levels of metabolic stress which is thought to change with a high glucose intake.

What are the possible benefits and risks of participating?
The possible benefits include a better understanding of how your body responds to glucose and your overall vascular health. The EndoPAT testing can be uncomfortable and may bruise your arm; blood sampling may also leave a bruise. All the tests are routinely undertaken in clinical practice and are considered safe for people with diabetes.

Where is the study run from?
The Clinical Trials Unit, Michael White Diabetes Centre, Anlaby Road, Hull.

When is the study starting and how long is it expected to run for?
The study started in January 2009 and is expected to run for 3 months.

Who is funding the study?
Barry Callebaut BV, Lebbeke-Weise, Belgium.

Who is the main contact?
Professor Stephen Atkin, Head of Academic Metabolism, Endocrinology and Metabolism.

# 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

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
BC 1

# Study information

### Scientific Title
High polyphenol chocolate effects on endothelial reactivity acutely in type 2 diabetes: a double-blind placebo controlled study

### Acronym
ChocOGTT

### Study objectives
Polyphenols in chocolate reduce the endothelial irritation caused by a glucose load.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Hull and East Riding Local Research Ethics Committee, approved on 18/03/2008 (ref: 08/H1304 /5)

### Study design
Double-blind randomised controlled 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
Pre-loading subjects with water with 13.5 g chocolate with or without polyphenols prior to oral glucose tolerance test.

### Intervention Type
Drug

### Phase

Not Applicable

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

### Primary outcome measure
Improved endothelial function as measured by EndoPAT™. Endothelial function was assessed before consumption of the chocolate, then at 60 and 180 min following consumption of the chocolate.

### Secondary outcome measures
1. Insulin response
2. C-reactive protein (CRP)

The secondary outcomes were measured before consumption of the chocolate, then every 30 min until 180 min after consumption of the chocolate.

### Overall study start date
01/01/2009

### Completion date
01/05/2009

## Eligibility

### Key inclusion criteria
1. Male or post menopausal female, aged between 40-75
2. Type 2 diabetes
3. Managed with diet or exercise alone or metformin
4. Stable medication

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
12

### Key exclusion criteria
1. Unwilling to allow contact with GP
2. Diabetes treated with other agents

### Date of first enrolment
01/01/2009

**Date of final enrolment**
01/05/2009

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Brocklehurst Building**
Hull
United Kingdom
HU3 2RW

# Sponsor information

**Organisation**
Barry Callebaut (Belgium)

**Sponsor details**
c/o Leen Allegaert
Innovations
Aalstersestraat 122
Lebbeke
Belgium
B-9280

**Sponsor type**
Industry

**Website**
http://www.barry-callebaut.com/

**ROR**
https://ror.org/053ax5y02

# Funder(s)

**Funder type**
Industry

**Funder Name**
Barry Callebaut (Belgium)

# 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 | 01/04/2013 | | Yes | No |