

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

Submission date 03/09/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol ☐ Statistical analysis plan ☒ Results ☐ Individual participant data
Registration date 22/09/2009	Overall study status Completed	
Last Edited 15/08/2013	Condition category 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

Protocol serial number

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)

Primary study design

Interventional

Study design

Double-blind randomised controlled trial

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Brocklehurst Building

Hull

United Kingdom

HU3 2RW

Sponsor information

Organisation

Barry Callebaut (Belgium)

ROR

<https://ror.org/053ax5y02>

Funder(s)

Funder type

Industry

Funder Name

Barry Callebaut (Belgium)

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	01/04/2013		Yes	No