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Diet and Vascular Health

Submission date	Recruitment status	[_] Prospectively registered
29/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/07/2016	Circulatory System	

Plain English summary of protocol

Background and study aims
Cardiovascular disease (CVD) is one of the main causes of early death in the UK. In England more than 110,000 people die every year of coronary heart disease. More than 1.4 million people suffer from angina and annually about 275,000 people have a heart attack. CVD is complex, and usually results from a narrowing of the arteries (atherosclerosis) and/or a blockage through the formation of a blood clot in a narrowed artery (thrombosis). These events have been found to be associated with changes in the bloodstream like increasing aggregation of platelets, increases in plasma fats (lipids) and an increase in compounds associated with inflammation. Of these, inflammation is of central importance, and may be involved in the development of other forms of chronic disease such as cancer and cognitive decline.
Advice to eat at least five portions of fruit and vegetable per day is largely based upon data from studies that have found diets rich in fruits and vegetables to be associated with a reduction in age-related chronic illness. While studies tend to focus on vascular health, risk of cancer or cognitive decline, several components in the diet may have beneficial effects on a range of age-related chronic diseases. For example, diets rich in certain polyphenols, n-3 fatty acids and cruciferous vegetables have all been associated with a reduction in the risk of CVD and cancer, with polyphenols and n-3 fatty acids associated with a reduction in cognitive decline. These compounds may work by reducing the rate of age-related increases in inflammation, thereby reducing the chances of tissues/organs developing chronic conditions.
Broccoli contains substances known as glucosinolates, which are converted by the body to isothiocyanates when eaten. The major glucosinolate in broccoli is glucoraphanin, which produces the isothiocyanate called sulforaphane. The glucosinolates are thought to be the main component in broccoli that may reduce CVD risk. In our study we will use a standard type of broccoli and a type that has higher levels of glucosinolates (called HG broccoli).
The aim of this study is to examine the effects of a diet rich in broccoli on CVD risk using indicators such as cholesterol levels and markers of inflammation, as well as established measurements such as blood pressure measurements.

Who can participate?
A total of 54 men and women aged 50 years old and above who have a mild to moderate risk of developing CVD or having a cardiovascular event over the next 10 years.

What does the study involve?
Participants will be randomly allocated into one of three groups. Over a 12-week period,

participants in group 1 will eat 400 g of standard broccoli each week, those in group 2 will eat 400 g of HG broccoli each week, and those in group 3 will eat 400 g of peas each week. Volunteers will be able choose which day to eat the vegetables, but will be asked to keep a record of when the vegetables were eaten. A number of tests will be performed on the volunteers before and after the study; blood samples will be taken to determine the concentration of lipids in their blood as well as a number of CVD risk indicators.
We appreciate that volunteers may wish to go on holiday during the study. Volunteers will be allowed to go on holiday for up to 7 days during the course of the intervention, provided they are able to incorporate the broccoli/peas that would have been eaten during those 7 days in the week prior to and following their trip. We will ask the volunteers to inform us of any planned holiday dates so that we can keep a record and alter their clinical study days accordingly. We will ask them to avoid booking holidays for more than 7 days at a time, especially either side of their visits to the clinic.

What are the possible benefits and risks of participating?
There are no direct benefits for the participants. Our results will help us to understand how eating vegetables like broccoli protects against age-related diseases including CVD, and allow us to develop more specific public health advice.
The risks are associated with obtaining blood samples and some of the measurements. As with any blood sample, there can be a small amount of discomfort on insertion of the needle, which affects some people more than others. The volunteer should not experience pain during the procedure or afterwards. The volunteer may develop a small bruise at the site of the blood sample, but this will fade like any bruise. As with any pressure measurement (like blood pressure), the inflation of the cuffs may cause slight discomfort. The inflation of the leg cuff is similar to the inflation of the arm cuff when having your blood pressure taken, and the inflation of the neck cuff is similar to wearing a loose fitting tie. There is a 24-hour period before your clinical appointment when you will not be allowed to have drinks containing caffeine. For those who drink a lot of tea or coffee, this may cause a mild headache.

Where is the study run from?
The study will be carried out over two sites: the Human Nutrition Unit at the Institute of Food Research, and the Clinical Research and Trials Unit at the Norfolk and Norwich University Hospital based at University of East Anglia.

When is the study starting and how long is it expected to run for?
The study started in January 2010 and finished in August 2010.

Who is funding the study?
It is funded by the Biotechnology and Biological Sciences Research Council (BBSRC) and a private company called Seminis (www.seminis.com).

Who is the main contact?
The study will be led by Professor Richard Mithen (Institute of Food Research, Norwich) and Professor John Potter (University of East Anglia, Norwich) and run by Dr Charlotte N Armah (Institute of Food Research, Colney Lane, Norwich NR4 7UA; 01603 255 360).

Contact information

Type(s)
Scientific

Contact name
Dr Charlotte Armah

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01114399

Secondary identifying numbers
7740

Study information

Scientific Title
The effects of a diet rich in broccoli on cardiovascular disease risk in adults: a randomised interventional prevention trial

Study objectives
The aim of this study is to examine the effects of a diet rich in broccoli on cardiovascular disease risk using biochemical indicators such as blood lipid profiles, most notably cholesterol; markers of inflammation as well as established physiological measurements such as pulse wave velocity (PWV), augmentation index (AIx) and ambulatory blood pressure measurements (ABPM). Broccoli contains compounds know as glucosinolates which are metabolised to isothiocyanates when consumed. The major glucosinolate in broccoli is known as glucoraphanin which produces the isothiocyanate sulforaphane. The glucosinolates are thought to be the principal component in broccoli that may reduce CVD risk. We will use a standard cultivar of broccoli and a cultivar that has enhanced levels of glucosinolates (HG broccoli). This broccoli has been used in previous intervention studies (e.g. ClinicalTrials.gov NCT00535977). Volunteers will be asked to consume 400g of standard broccoli, HG broccoli or peas each week over a 12 week period in a double blinded (for the broccoli) parallel study. The volunteers recruited will, according to the Joint British Societies (JBS 2) Guidelines on the prevention of cardiovascular disease (CVD) in clinical practise, have a 10-20% (mild to moderate) risk of developing cardiovascular disease or having a cardiovascular (CV) event in the next 10 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Hertfordshire Research Ethics Committee (REC) approved on the 7th October 2009 (ref: 09 /H0311/96)

Study design
Randomised interventional prevention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Cardiovascular; Subtopic: Not Assigned, Cardiovascular (all Subtopics); Disease: Cardiovascular, All Diseases

Interventions
The volunteers will be matched for gender while being assigned to one of 3 study groups:
1. One group will consume 400 g of standard broccoli each week for 12 weeks
2. The second group will consume 400 g of the high glucosinolate broccoli each week for 12 weeks
3. The third group will consume 400 g of peas each week for 12 weeks

The broccoli and the peas will be consumed on top of the volunteer's standard diet.

Once the volunteers have completed their final visit to the CRTU after 12 weeks of the intervention, there will be no further contact.
Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Cholesterol, measured at baseline and week 12

Secondary outcome measures
Genotyping, measured at baseline

Overall study start date
04/01/2010

Completion date
31/08/2010

Eligibility

Key inclusion criteria
1. Men and women aged greater than or equal to 50 years
2. Recruited onto the study using the JBS cardiac risk assessor calculator. Scores of 1020% will be acceptable for participation in the study.
3. Total cholesterol greater than or equal to 5.0 mmol/L
4. Blood pressure measurements: systolic greater than or equal to 120 mmHg, diastolic greater than or equal to 80 mmHg
5. Body mass index (BMI) greater than 20 kg/m^2

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
Planned Sample Size: 54; UK Sample Size: 54

Key exclusion criteria
1. Diagnosed diabetics
2. Fasting glucose greater than 6 mmol/L
3. Blood pressure less than 90/50 mmHg or 95/95 mmHg if symptomatic; greater than 160/100 mmHg
4. Chronic kidney disease
5. Those on hypolipidemic therapy
6. Those who have suffered a cardiovascular event like stroke, myocardial infarction, trans ischemic attacks etc within 2 years
8. Peripheral vascular disease including claudication
9. Consumption of fish oil supplements (unless volunteer is willing to discontinue their use at least 4 weeks prior to intervention starting)
10. Parallel participation in another research project which involves dietary intervention and/or sampling of biological fluids/materials
11. Any person related or living with any member of the study team
12. Participation in another research project which involves blood sampling within the last four months; blood from both studies should not exceed 470 mL
13. BMI less than 20 kg/m^2 or BMI greater than 40 kg/m^2
14. Fasting total cholesterol greater than 8.0 mmol/L
15. Gastrointestinal disease (excluding hiatus hernia) unless symptomatic or study intervention /procedure is contraindicated

16. Going on holiday for more than 7 days in any single period or within 2 weeks of their clinical appointment at the CRTU
17. Currently suffering from or have suffered from any neck and throat injuries and surgery

Date of first enrolment
04/01/2010

Date of final enrolment
31/08/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Food Research
Norwich
United Kingdom
NR4 7UA

Sponsor information

Organisation
Institute of Food Research (UK)

Sponsor details
Norwich Research Park
Colney
Norwich
United Kingdom
NR4 7UA

Sponsor type
Research organisation

Website
http://www.ifr.ac.uk/

ROR
https://ror.org/04td3ys19

Funder(s)

Funder type
Research council

Funder Name
Biotechnology and Biological Science Research Council (BBSRC) (UK) (ref: IFR/08/4)

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	01/09/2013		Yes	No