ISRCTN92382106 https://doi.org/10.1186/ISRCTN92382106

Cardiovascular risk reduction study: supported by an integrated dietary approach

Submission date 04/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/10/2010	**Overall study status** Completed	
Last Edited 19/01/2017	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.medscinet.net/CRESSIDA/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N02047

Study information

Scientific Title
The effectiveness of an integrated cardioprotective dietary intervention compared with an average UK diet in reducing cardiovascular disease risk factors in older men and women aged 40 - 70 years

Acronym
CRESSIDA

Study objectives
An integrated dietary approach using a cardioprotective diet will significantly reduce cardiovascular disease (CVD) risk factors compared to the average UK diet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St. Thomas' Hospital Research Ethics Committee, April 2010, ref: 10/H0802/24

Study design
Randomised parallel-design single-centre controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Can be found at http://www.medscinet.net/CRESSIDA

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
This is a controlled dietary intervention trial comparing a cardioprotective diet (decreased salt and saturated fatty acids intake, and increased wholegrain cereals, fruit and vegetables and oily fish intake) with a control diet (average UK diet) for 3 months.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
A change in systolic blood pressure (BP) measured by ambulatory blood pressure, a change in endothelial function measured by flow-mediated dilation, and a change in total/high density lipoprotein (HDL) cholesterol ratio measured at baseline and 3 months.

Secondary outcome measures
1. A change in arterial stiffness (pulse wave velocity and digital volume pulse), measured at baseline and 3 months
2. A change in insulin sensitivity (revised quantitative insulin sensitivity test [RQUICKI] and serum adiponectin), measured at baseline and 3 months
3. A change in C-reactive protein concentrations, measured at baseline and 3 months

Overall study start date
16/07/2010

Completion date
30/06/2012

Eligibility

Key inclusion criteria
Healthy men and women, aged 40 - 70 years

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
196

Key exclusion criteria
1. A reported history of angina, myocardial infarction, peripheral vascular disease, congenital heart disease or stroke
2. Asymptomatic atrial fibrillation
3. Type 1 or type 2 diabetes mellitus (fasting plasma glucose greater than 7 mmol/L)
4. Seated blood pressure greater than 160/105 mmHg
5. Current use of medication for lowering blood cholesterol (statins) or blood pressure
6. Body mass index less than 18.5 and greater than 35 kg/m2
7. An overall risk of cardiovascular disease over the next ten years of greater than 20% assessed according to current NICE guidelines in combination with untreated high blood pressure or

raised cholesterol
8. Clinical history of cancer (excluding basal cell carcinoma) in the past five years
9. Chronic renal, liver or inflammatory bowel disease
10. Current cigarette smoker (confirmed by urinary cotinine analysis)
11. History of substance abuse or alcoholism (previous weekly alcohol intake greater than 60 units/men or 50 units/women)
12. Current self-reported weekly alcohol intake not exceeding 21 units for women and 28 for men
13. Currently pregnant, planning pregnancy or having had a baby in the last 12 months
14. Unwilling to follow the protocol and/or give informed consent
15. Unwilling to refrain from use of dietary supplements
16. Unwilling to restrict consumption of oily fish
17. Weight change of greater than 3 kg in preceding 2 months

Date of first enrolment
16/07/2010

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nutritional Science Division
London
United Kingdom
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Sponsor information

Organisation
King's College London (KCL) (UK)

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Sponsor type
University/education

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

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
Food Standards Agency (FSA) (UK) (ref: N02047)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/05/2015		Yes	No
Results article	results	01/04/2017		Yes	No
Results article	results	01/06/2017		Yes	No