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Battle of the Bulge - a randomised study comparing the effect of three dietary approaches on cardiovascular risk in subjects with the metabolic syndrome

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
17/05/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0212177254

Study information

Scientific Title
Battle of the Bulge - a randomised study comparing the effect of three dietary approaches on cardiovascular risk in subjects with the metabolic syndrome

Study objectives
To compare the effectiveness of three dietary regimes in improving cardiovascular risk in subjects with the metabolic syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Metabolic syndrome

Interventions
Comparison of three dietary approaches

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Improving the cardiovascular risks associated with the metabolic syndrome has long-term beneficial effects on health and quality of life. Management through dietary lifestyle changes is possibly the healthier option with less chances of side effects or interactions as would be expected through drugs.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/05/2007

Eligibility

Key inclusion criteria

Males or non-pregnant females fulfilling the criteria for the metabolic syndrome - these include the presence of three or more of the following:
1. Abdominal obesity (waist circumference >102 cm in men and >88 cm in women)
2. Triglyceride level >150 mg/dl
3. HDL cholesterol <40 mg/dl for men, <50 mg/dL for women
4. Blood pressure >130 mm systolic or 85 mm diastolic
5. Fasting plasma glucose >6.1 mmol/dl

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Recent cardiovascular event, i.e. stroke, myocardial infarction or pulmonary embolism, within past 4 months
2. Ongoing chronic inflammatory condition: vasculitis, ulcers, inflammatory bowel disease, malignant disorder
3. Renal impairment (creatinine >135)
4. Hepatic impairment (ALT or AST> 4x upper limit of normal)
5. On statin therapy for dyslipaemia
6. Poorly controlled diabetes. Type 2 diabetes on insulin therapy. Type 2 diabetes on thiazolidinione
7. Untreated thyroid disorders - should be stable on thyroid medication for at least 3 months
8. Known Cushing's syndrome
9. On an anorectic agent, i.e., Orlistat, sibutramine - can be given a 4-week washout period
10. Food allergies/intolerance
11. Vegetarian

Date of first enrolment
01/03/2004

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal United Hospital
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Royal United Hospital Bath NHS Trust (UK)

Funder Name
Diabetes Research Fund

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration