

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	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/05/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2004

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

Age group

Adult

Sex

Both

Target number of participants

120 - recruitment is completed as of July 2008

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 thiazolidinone
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

England

United Kingdom

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)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Royal United Hospital Bath NHS Trust (UK)

Funder Name

Diabetes Research Fund

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