ISRCTN84550872 https://doi.org/10.1186/ISRCTN84550872

Effects of a Nordic breakfast on cardiovascular risk factors.

Submission date	Recruitment status
04/12/2009	No longer recruiting
Registration date	**Overall study status**
07/01/2010	Completed
Last Edited	**Condition category**
14/05/2014	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
North B U-08-017

Study information

Scientific Title
Effects of a Nordic breakfast diet on risk markers for cardiovascular disease in healthy mildly hypercholesterolemic men and women.

Acronym
North B

Study objectives
The aim of this study is to investigate if intake of a healthy Nordic breakfast may affect risk markers for cardiovascular disease in healthy mildly hypercholesterolemic men and women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the regional ethic committee in Uppsala, on the 20th of January 2009 (ref: North B U-08-017, Dnr 2009/018)

Study design
Randomised controlled parallel group intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Cardiovascular risk factors

Interventions
The test breakfast will include: Porridge made of oat bran. Low fat milk or yoghurt. A choice of jam (blueberries or lingonberries). Whole grain bread. Margarine with high content of polyunsaturated fatty acids (19%). Something to put on the bread such as low fat meat or pickled herring or mackerel in tomato. Fresh fruit will also be included.

Outcomes after intake of a Nordic breakfast diet in comparison to ordinary foods in mildly hypercholesterolemic men and women, (LDL-cholesterol levels > 3.0 mmol/l) will be measured after 12 weeks. There will be no follow up beyond the end of the 12 week intervention.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
The effect on LDL-cholesterol will be measured at baseline, 6 and 12 weeks.

Secondary outcome measures
The following will be measured at baseline, 6 and 12 weeks
1. HDL cholesterol
2. Total cholesterol
3. Triglycerides
4. High-Sensitivity C-Reactive Protein (HS-CRP)
5. Apolipoprotein A1 and B
6. Blood pressure
7. Sagittal abdominal diameter (SAG)
8. Hip
9. Waist
10. Glycated Haemoglobin (HbA1c)
The following will be measured at baseline and 12 weeks
11. Glucose response
12. Insulin sensitivity

Overall study start date
01/06/2009

Completion date
30/01/2010

Eligibility

Key inclusion criteria
1. Slightly overweight and hyperlipidemic but otherwise healthy as assessed by the results of the screening laboratory tests and judged by medical staff
2. Age ≥ 25 and ≤ 67 years at visit 1
3. Body Mass Index (BMI) ≥ 25 and ≤ 35 kg/m2
4. LDL cholesterol ≥ 3.0 mmol/l
5. Haemoglobin (Hb) ≥ 120 g/l for women and ≥ 130 g/l for men
6. Signed written informed and biobank consents

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
88

Key exclusion criteria
1. Participation in a clinical study with blood sampling within 90 days prior to screening visit and throughout the study.
2. Use of cholesterol lowering medication <3 months prior screening visit.
3. Blood pressure >155/95 (will be measured at visit 1 for inclusion).
4. Consumption of products or supplements fortified with plant sterols or omega-3 or omega-6 or omega 9- fatty acids within 3 weeks prior to the visit 1 and no consumption at all throughout the study.
5. Allergic to certain foods
6. Slimming or medically prescribed diet/medication or a special diet (vegan and gluten-free).
7. Not able to eat porridge for breakfast every day during 12 weeks
8. Not able to eat herring or mackerel for breakfast 3 days/week during 12 weeks
9. Pregnant or lactating or wish to become pregnant during the period of the study.
10. Lack of suitability for participation in the study for any reason as judged by the personnel at Good Food Practice (GFP) research clinic.

Date of first enrolment
01/06/2009

Date of final enrolment
30/01/2010

Locations

Countries of recruitment
Sweden

Study participating centre
Clinical Nutrition and Metabolism
Uppsala
Sweden
751 85

Sponsor information

Organisation
University of Uppsala (Sweden)

Sponsor details
Clinical Nutrition and Metabolism
Departement of Public health and Caring Sciences
Uppsala Science Park

Uppsala
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Sponsor type
University/education

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Industry

Funder Name
Cerealia Foundation R&D (Sweden)

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	01/02/2015		Yes	No