

Effects of a Nordic Diet on cardiovascular risk factors

Submission date 24/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/12/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/12/2009	Condition category Circulatory System	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
U-07-009

Study information

Scientific Title

Effects of a Nordic Diet on cardiovascular risk factors in hypercholesterolemic subjects: a randomised controlled trial

Acronym

NORDIET

Study objectives

The aim of the study was to investigate the effects of a Nordic diet on cardiovascular risk factors in mildly hypercholesterolemic subjects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethics Committee in Uppsala approved on the 19th of December 2007 (ref: North D U-07-009 Dnr 2007/328)

Study design

Randomised controlled parallel-group study with voluntary free-living subjects

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet**Health condition(s) or problem(s) studied**

Cardiovascular risk factors

Interventions

Intervention Group - The Nordic Diet:

The nutrient profile of the Nordic Diet (ND) was based on Nordic nutrition recommendations 2004²³ and inspired by the Mediterranean diet, Portfolio diet, DASH diet and NCEP. The food profile was based on typical foods consumed in the Nordic countries and the nutrient profile is comparable to that of the Mediterranean diet, including LDL-C lowering foods.

Control group - care as usual.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Change in plasma LDL-C after 6 weeks

Secondary outcome measures

Change in:

1. Other blood lipids and apolipoproteins
2. Blood pressure
3. Insulin sensitivity (fasting insulin and homeostatic model assessment insulin resistance [HOMA-IR])

Overall study start date

20/12/2007

Completion date

15/05/2008

Eligibility

Key inclusion criteria

1. Men and women between 25 and 65 years of age
2. Healthy as assessed by a physician
3. Body mass index (BMI) greater than or equal to 20 and less than or equal to 31 kg/m²
4. Plasma low density lipoprotein cholesterol (LDL-C) greater than or equal to 3.5 mmol/l
5. Haemoglobin (Hb) greater than or equal to 120 g/l for women and greater than or equal to 130 g/l for men

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

88

Key exclusion criteria

1. Participation in a clinical study within 90 days prior to screening visit and throughout the study
2. Use of lipid lowering drugs two months prior screening and throughout the study
3. Blood pressure greater than 145/85 mmHg
4. Use of products or supplements fortified with plant sterols, omega-3, omega-6 or omega-9 fatty acids within 3 weeks prior to baseline visit
5. Allergy to certain foods
6. Weight-loss diets or drugs
7. Special diets (e.g. vegan and gluten free)
8. Pregnant or lactating

Date of first enrolment

20/12/2007

Date of final enrolment

15/05/2008

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

Department of Public Health and Caring Sciences

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Uppsala

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Sponsor type

University/education

Website

<http://www.uu.se>

ROR

<https://ror.org/048a87296>

Funder(s)

Funder type

Industry

Funder Name

The 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