

Nutrient-gene interaction in human obesity: implications for dietary guidelines

Submission date

28/03/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

04/05/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

14/07/2021

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

QLRT-2000-00618

Study information

Scientific Title

Genetic Polymorphisms and Weight Loss in Obesity: A Randomised Trial of Hypo-Energetic High-versus Low-Fat Diets

Acronym

NUGENOB

Study objectives

There is an interaction between nutrient composition of the diet - more specifically the fat content - and obesity-related genes in the response to dietary treatment of human obesity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study has received appropriate ethics committee approval. Denmark reference number: 01-083/01, 6/07/2001. The Netherlands: reference number: 01-058.3, 27/04/2001. Sweden: reference number: 127/01, 7/05/2001. United Kingdom reference number: GM040103, 14/05/2001. Czech Republic: 12/06/2001. France: reference number: 2-01-12/2, 30/03/2001. Spain: 5/04/2001.

Study design

Randomised parallel two-arm open-label trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obesity

Interventions

One-day clinical investigation examining responses to high fat test meal in lean and obese subjects followed by randomised, parallel, two-arm, open label, 10-week dietary intervention of two hypo-energetic diets with high and low fat content respectively in obese subjects.

Patients are randomised to receive two hypo-energetic diets with low-fat or high fat content.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Weight loss

Key secondary outcome(s)

1. Changes in waist circumference
2. Body composition assessed by bio-impedance
3. Fasting blood lipids
4. Insulin and glucose

Completion date

31/12/2002

Eligibility**Key inclusion criteria**

1. Body mass index (BMI) ≥ 30
2. White European (by self report)
3. Age 20-50 years
4. Pre-menopausal (women)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

755

Key exclusion criteria

1. Drug-treated hypertension
2. Drug-treated diabetes
3. Drug-treated hyperlipidaemia
4. Drug-treated thyroid disease
5. Use of anorexigenic agents
6. Anti-epileptic drugs
7. Anti-Parkinsonian drugs
8. Use of barbituates, benzodiasapines, beta-blockers, butyrophenones, carbonic anhydrase inhibitors, diuretics, dopamine reuptake inhibitors, digoxin, fibrates, fish oil supplement, glucocorticoids, immunosuppressives, insulin, laxatives, monoamine oxidase (MAO) inhibitors, niacin (>150 mg per day), nicotine, oral hypoglycemics, orlistat, phenothiazines, selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, statins, thyroid hormone, triamterene, tricyclic antidepressants, warfarin or zonisamide
9. Surgically-treated obesity
10. Participation in ongoing drug trials
11. Pregnant women
12. Alcohol or drug abuse
13. Weight change of >3 kg within 3 months prior to clinical investigation day

Date of first enrolment

01/05/2001

Date of final enrolment

31/12/2002

Locations

Countries of recruitment

United Kingdom

Czech Republic

Denmark

France

Netherlands

Spain

Sweden

Study participating centre

H:S Institute of Preventive Medicine

Copenhagen

Denmark

DK-1357

Sponsor information

Organisation

European Commission, Research Directorate-General (Belgium)

ROR

<https://ror.org/00k4n6c32>

Funder(s)

Funder type

Other

Funder Name

European Commission, 5th Framework Programme: Quality of Life and Management of Living Resources - Key Action I: Food, Nutrition and Health" (QLRT-2000-00618)

Results and Publications

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	01/06/2006		Yes	No
Results article	results	01/06/2012		Yes	No
Results article		13/07/2021	14/07/2021	Yes	No