ISRCTN25867281 https://doi.org/10.1186/ISRCTN25867281

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

Submission date	Recruitment status	[_] Prospectively registered
28/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/07/2021	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Thorkild Sørensen

Contact details
H:S Institute of Preventive Medicine
Øster Søgade 18, 1
Copenhagen
Denmark
DK-1357
+45 (0)3338 3880
tias@ipm.hosp.dk

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.

Primary study design
Interventional

Study design
Randomised parallel two-arm open-label trial

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