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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
28/03/2006		☐ Protocol		
<b>Registration date</b> 04/05/2006	Overall study status Completed	Statistical analysis plan		
		[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

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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 Highversus 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

## 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