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Adherence to Mediterranean diet can reduce the risk of obesity in people with genetic predisposition to obesity

Submission date
23/07/2017

Recruitment status
No longer recruiting

Registration date
02/08/2017

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The obesity epidemic worldwide is fast increasing and affecting individuals of all ages, races and both genders. It is related with a series of other issues including diabetes, hypertension, cancer and cardiovascular diseases. Obesity is caused by genetic and environmental factors such as over-consumption of energy and sedentary lifestyle. Of genetic variants, fat mass and the obesity associated gene (FTO) have been found to be consistently associated with obesity traits in several populations. However there is increasing interest in finding out whether lifestyle factors modify the association of FTO variants and obesity as this could better provide insight into the role of diet/environmental factors in obesity. The Mediterranean diet is a diet that is high in vegetables, olive oil and fish (lean sources of protein). A higher adherence to the Mediterranean dietary pattern (Med Diet) using Mediterranean diet scores (MDS) has been associated with a decrease in obesity, regardless of genetic risk. This study uses participants in the Tehran Lipid and Glucose Study (TLGS). The TLGS is a large-scale, community-based, prospective study being performed on a sample of residents of District 13 of Tehran, capital of Iran. The first phase of the TLGS was conducted from 1999 to 2001 and follow-up examinations have been conducted every 3 years (2002–2005; 2006–2008; 2008–2011, and 2011–2014) to identify newly developed diseases. The aim of this study is to investigate whether Med Diet could interact with FTO in relation to obesity among adult participants in order to identify environmental interactions to create preventive approaches in individuals with greater genetic susceptibility to obesity.

Who can participate?
Adults aged 18 years and older.

What does the study involve?
Participants undergo a baseline survey. Those who are evaluated as obese are excluded. The other participants are followed and randomly selected for follow-up surveys.The surveys include questions about food frequency and types of food ingested in order to provide a MDS score to participants. Other measures such as physical activity, smoking, and other demographics are also assessed. DNA samples are provided by participants in order to identify their genetic risk.

What are the possible benefits and risks of participating?
Participants may help prevent obesity in those with FTO risk alleles. There are no risks with participating.

Where is the study run from?
This study is run by the Shahid Beheshti Univeristy of Medical Sciences (Iran) and the TLGS is performed on a sample of residents of District 13 of Tehran (Iran).

When is the study starting and how long is it expected to run for?
February 1998 to February 2017

Who is funding the study?
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences (Iran)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Research Institute for Endocrine Sciences (Grant No. 840), Shahid Beheshti University of Medical Sciences

Study information

Scientific Title
Mediterranean dietary pattern adherence modify the association between FTO genetic variations and obesity phenotypes

Study objectives
Can Mediterranean Diet interact with FTO gene polymorphisms (rs1121980, rs1421085, rs9939973, rs8050136, rs17817449 and rs3751812) in isolation or combined form (GRS) in relation to obesity phenotypes among participants of the Tehran Lipid and Glucose Study (TLGS)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, 10/01/1999, ref: 840

Study design
Observational-nested case-control study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Obesity

Interventions

Participants undergo a baseline survey. Those who are evaluated as obese are excluded. The other participants are followed and randomly selected for follow-up surveys between 2006-2008, 2008-2011 and 2011-2014. Each of these cases are individually paired and matched by age (plus or minus five years), sex and duration of follow-up with a random control from a population with normal body mass index. The duration of follow-up is from baseline to the follow up survey which marks the end of their participation in the study.

The survey that participants fill out assessed participants dietary intakes using a valid and reliable 168-item semi-quantitative food frequency questionnaire (FFQ) at baseline and follow up surveys. The Mediterranean dietary score is computed according to richopoulou et al. based on the following eight components: Legumes, vegetables, nuts and fruits, fish, and cereals intake; dietary ratio of monounsaturated fatty acid (MUFA) to saturated fatty acid (SFA); intake of dairy products, mostly in the form of cheese or yogurt and intakes of meat and poultry. The anthropometric, physical activity, smoking and the other demographic variables are assessed at baseline and follow-up surveys, DNA products of participants were genotyped and genetic risk score is computed.
The risk of obesity (odds ratio) of individuals with different genetic risk scores assessed across the Mediterranean dietary score quartiles from baseline to follow-up survey.

Intervention Type
Other

Primary outcome(s)
1. Weight is measured using the digital scales at baseline and each follow-up examination (every three years)
2. Height is measured using a tape measure at baseline and each follow-up examination (every three years)
3. Waist circumference is measured using the upstretched tape meter at baseline and each follow-up examination (every three years)
4. Hip circumference is measured using the upstretched tape meter at baseline and each follow-up examination (every three years)

Key secondary outcome(s))
1. BMI (body mass index) is calculated by dividing weight in kilograms on height in meters squared baseline (kg/m2) at baseline and each follow-up examination (every three years)
2. WHR (waist to hip ratio) is calculated by dividing waist on hip circumferences at baseline and each follow-up examination (every three years)
3. Obesity was defined as a BMI ≥30 kg/m2
4. BMI between 18.5 and 24.9 classified a person as having a normal weight
5. Waist circumference >95 cm for both genders was considered as indicators of abdominal obesity
6. WHR >0.8 in men and >0.9 in women, was considered as indicators of abdominal obesity

Completion date
15/02/2017

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Both genders

3. Participating in baseline and follow-up examinations of Tehran Lipid and Glucose Study
4. BMI≥30 for cases, BMI≥18.5 and <25 for controls.
5. Not pregnant or lactating women
6. Not history of weight loss or gain >5 kg in the last 6 months
7. Not taking drugs that affect weight
8. Not under or over-reporters of energy intake
9. DNA purification in the range of 1.7<A260/A280<2

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1000

Key exclusion criteria
1. Individuals with a history of weight loss or gain >5 kg in the last 6 months
2. Pregnant and lactating
3. Taken drugs that affect weight
4. Cases/controls lacking DNA purification in the range of 1.7<A260/A280<2
5. Reported energy intakes divided by the predicted energy intake did not qualify for the ±3SD range

Date of first enrolment
31/01/1999

Date of final enrolment
20/01/2015

Locations

Countries of recruitment
Iran

Study participating centre
Shahid Beheshti University of Medical Sciences
Nutrition and Endocrine Research Center
Research Institute for Endocrine Sciences

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Sponsor information

Organisation
Shahid Beheshti University of Medical Sciences

ROR
https://ror.org/034m2b326

Funder(s)

Funder type
Not defined

Funder Name
Shahid Beheshti University of Medical Sciences

Alternative Name(s)
Shahid Beheshti University of Medical Sciences (SBMU), Iran, Shahid Beheshti University of Medical Sciences (Iran), Shahid Beheshti University of Medical Sciences - Iran, , Université des Sciences Médicales de Shahid Beheshti, , Shahid Beheshti University of Medical Sciences Tehran Iran, Shahid Beheshti University of Medical Sciences Tehran, Université des Sciences Médicales de, , , SBUMS

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Iran

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Amir-Abbas Momenan at momenan@gmail.com or momenan@endocrine.ac.ir

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results (phase one)	01/05/2002		Yes	No
Results article	results (phase two) in	25/01/2009		Yes	No
Results article		26/09/2017	20/09/2023	Yes	No