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Differences in blood metabolic and molecular biomarkers among normal weight, mildly obese, and moderately obese subjects

Submission date
29/04/2015

Recruitment status
No longer recruiting

Registration date
07/05/2015

Overall study status
Completed

Last Edited
10/03/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity is a term used to describe somebody who is very overweight, with a lot of body fat. It's a common problem, estimated to affect around one in every four adults and around one in every five children aged 10 to 11 in the UK. People who are obese are at risk of a number of serious and potentially life-threatening conditions, such as cardiovascular disease, particularly if the disease is diagnosed at a late stage. Biomarkers (biological markers) are molecules that come from cells which can be found circulating in a person's blood. Scientists can use these biomarkers as a way of detecting changes in a person's body at the very earliest stages of disease. The aim of this study is to examine biomarkers found in specific blood cells called peripheral blood mononuclear cells (PBMCs). PBMCs of obese patients will be compared with those found in healthy patients to see if there are any differences that might indicate signs of early disease. This study will also compare the genes of PBMCs to see whether they might be useful for early diagnosis and treatment of obesity-related disturbances in a person's metabolism.

Who can participate?
Men of either healthy weight or diagnosed obese.

What does the study involve?
Participants are divided into groups according to their body mass index (BMI) calculation. All participants are asked to give a blood sample which is then tested for various biomarkers associated with health and disease.

What are the possible benefits and risks of participating?
The results of this study could potentially be used as a way to diagnose and manage obesity. Participants will be asked to provide a blood sample and may experience minor discomfort from this.

Where is the study run from?
Kyungpook National University (South Korea)

When is the study starting and how long is it expected to run for?
May 2012 to April 2013

Who is funding the study?
1. SRC Program (South Korea)
2. Fundamental Technology Program (South Korea)

Who is the main contact?
Dr UJ Jung

Contact information

Type(s)
Scientific

Contact name
Mr Un Ju Jung

Contact details
Kyungpook National University
Department of Food Science and Nutrition
1370 San-Kyuk Dong
Puk-Ku
Daegu
Korea, South
702-701

Additional identifiers

Study information

Scientific Title
Differences in metabolic biomarkers in the blood and gene expression profiles of peripheral blood mononuclear cells among normal weight, mildly obese, and moderately obese subjects

Study objectives
This study aims to establish metabolic and molecular differences among normal weight (BMI, 18.5~23 kg/m2), mildly obese (BMI, 25~27.5 kg/m2), and moderately obese (BMI, 27.5~30 kg/m2) Korean adult men. Levels of lipids, apolipoproteins, adipocytokines and markers of insulin resistance, oxidative stress, and liver damage in the plasma or erythrocytes will be tested alongside the gene expression profiles of peripheral blood mononuclear cells (PBMCs) using microarray analysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kyungpook National University Human Research Committee. ref: 2012-2.

Study design

Cross sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Blood biomarkers of people classified as normal weight, mildly obese and moderately obese according to body mass index (BMI) calculation.

Interventions
Participants are divided into groups according to their BMI: (1) mildly obese subjects (BMI between ≥25 and <27.5 kg/m2; n = 14), (2) moderately obese subjects (BMI between ≥27.5 and <30 kg/m2; n = 12) and (3) control group normal weight range (BMI between ≥18.5 and <23 kg /m2). All participants provide blood samples for screening.

Intervention Type
Other

Primary outcome(s)
1. Leptin, lipids (LDL- and HDL-cholesterol), apolipoprotein B levels and adiponectin
2. Circulating levels of inflammatory cytokines and markers of insulin resistance, oxidative stress, and liver damage.

Key secondary outcome(s))
1. PBMC transcriptome data
2. Signaling pathways: oxidative phosphorylation; triglyceride synthesis; carbohydrate metabolism; insulin, mTOR, FOXO, RAP1, RAS, and TGF-β signaling; and ECM–receptor interaction.

Completion date
30/04/2013

Eligibility

Key inclusion criteria
1. Participants classed as obese, having a BMI of 25~30 kg/m2 and a normal medical history
2. Healthy participants having a BMI 18.5~23 kg/m2

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. History of cancer or cardiac, renal, hepatic, or infectious disease.
2. Current treatment with insulin
3. Current use of drugs for controlling blood glucose, blood lipids and body weight.
4. History of gastrointestinal surgery
5. Consumption of functional foods or medications that may affect the results of this study

Date of first enrolment
01/06/2012

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
Korea, South

Study participating centre
Center for Food and Nutritional Genomics Research
Kyungpook National University, 1370 San-Kyuk Dong, Puk-Ku
Daegu
Korea, South
702-701

Sponsor information

Organisation
Kyungpook National University

ROR
https://ror.org/040c17130

Funder(s)

Funder type
Research organisation

Funder Name
SRC program (grant number 2015R1A5A6001906)

Funder Name
Fundamental Technology Program (South Korea)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration