

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/05/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/03/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/05/2012

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

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

37

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

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702-701

Sponsor information

Organisation

Kyungpook National University

Sponsor details

1370 San-Kyuk Dong, Puk-Ku

Daegu

Korea, South

702-701

Sponsor type

University/education

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

Publication and dissemination plan

Not provided at time of registration.

Intention to publish date

31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration