

# Effect of high-fat, high-carbohydrate meals in human

**Submission date**  
21/07/2010

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
05/08/2010

**Overall study status**  
Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**  
05/08/2010

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Sung Soo Kim

### 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

Antioxidant enzymes induced by repeated intake of high-fat, high-carbohydrate meals are not sufficient to block oxidative stress in healthy lean subjects: A randomised controlled trial

### Study objectives

We hypothesised that repeated intake of high-fat, high-carbohydrate meals would increase oxidative stress and insulin resistance, and alter the expression of anti-oxidant enzymes and mitochondria electron transport chain complex subunits.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Kyung Hee University Hospital Institutional Review Board approved on the 26th of April 2010 (ref: 1003-01-a3)

### Study design

Single centre randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Other

### Participant information sheet

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

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

Diet; oxidative stress; insulin resistance; protein dynamics

### Interventions

Ten healthy, lean male Korean subjects were enrolled in this study. Subjects started a standardized diet for 7 days with control meals for breakfast, lunch and dinner, based on the Dietary Reference Intake for Koreans (KDRI) guidelines. Blood samples were collected at 2 hours after lunch on day 7 during intake period of KDRI control meals for the standardized diet. After the standardized diet, five subjects continually ingested KDRI control meals for breakfast, lunch and dinner, and the other five subjects ate HFHC meals only for lunch daily for 4 days.

We used western blot analysis to check the expression of related proteins and fluorescence-activated cell sorting analysis to confirm reactive oxygen species levels. To check blood glucose and insulin levels, oral glucose tolerance test was conducted for the subjects.

#### **Results:**

We showed that expression of anti-oxidant enzymes and mitochondria transport chain complex subunits was increased following high-fat, high-carbohydrate meals for 4 day in blood mononuclear cells, compared with that following control meals on day 7. However, there was an increase in intracytosolic lipid peroxidation and the induction of SOCS-3 which interferes with insulin signal transduction, indicating that oxidative stress was still progressing.

#### **Intervention Type**

Other

#### **Phase**

Not Applicable

#### **Primary outcome measure**

1. Oxidative stress
2. Anti-oxidant enzyme expressions
3. Mitochondria transport chain complex subunits expressions

#### **Secondary outcome measures**

Insulin resistance

#### **Overall study start date**

06/05/2010

#### **Completion date**

20/05/2010

## **Eligibility**

#### **Key inclusion criteria**

1. Healthy volunteers
2. Age 28 - 32 years
3. Male
4. Body Mass Index (BMI): 18.5 - 22.9

#### **Participant type(s)**

Healthy volunteer

#### **Age group**

Adult

#### **Lower age limit**

18 Years

#### **Sex**

Male

**Target number of participants**

10 subjects

**Key exclusion criteria**

1. Complete Blood Count (CBC): white blood cells - more than 6,000/ul
2. Fasting blood sugar test: blood sugar concentration - more than 100 mg/dl
3. Haemoglobin A1c: more than 6.0%

**Date of first enrolment**

06/05/2010

**Date of final enrolment**

20/05/2010

**Locations****Countries of recruitment**

Korea, South

**Study participating centre**

Department of Biochemistry and Molecular Biology

Seoul

Korea, South

130-701

**Sponsor information****Organisation**

Kyung Hee University Medical Hospital (South Korea)

**Sponsor details**

c/o Sung Soo Kim

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**Sponsor type**

University/education

**ROR**

<https://ror.org/01vbmek33>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Korean Government (South Korea) - Grant for Prof Sung Soo Kim (MEST NO: 20090091346)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration