

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

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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