ISRCTN04309078 https://doi.org/10.1186/ISRCTN04309078

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

Submission date	Recruitment status	[ ] Prospectively registered
21/07/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/08/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/08/2010	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Other

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

Key secondary outcome(s))
Insulin resistance

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes