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Glycometabolism and lipid metabolism in obese people by metabolomics technique

Submission date	Recruitment status	[ ] Prospectively registered
24/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/05/2010	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
30872104

Study information

Scientific Title
A study of supplementation with multivitamins and minerals on glycometabolism and lipid metabolism in obese people by metabolomics technique: a randomised cross-over design trial

Acronym
SMUMGLMT

Study objectives
The effects of supplementation with multivitamin and mineral on the biomarkers of glycometabolic and lipid metabolic disorders and correlated basic metabolic rate (BMR), and the effects of the metabolic fingerprints in obese people.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of Public Health College, Harbin Medical University approved ethical review (001) on the 25th February 2010

Study design
Randomised cross-over trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Disorders of glycometabolism and lipid metabolism

Interventions
1. Experimental group: 2 months multivitamin and mineral intervention
2. Control group: no intervention

After 2 months, interchange the two groups.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Multivitamin and mineral supplementation

Primary outcome(s)
Metabolic fingerprints

Key secondary outcome(s))
1. Body height
2. Body weight
3. Waist circumference
4. Hip circumference

5. Basal metabolic rate (BMR)
6. Blood pressure
7. Body fat
8. Blood glucose
9. Blood fat
10. Endogenous creatinine clearance rate

Completion date
30/04/2010

Eligibility

Key inclusion criteria
1. Normal weight group: body mass index between 18.5 kg/m^2 - 24 kg/m^2
2. Obese group:
2.1. Body mass index (BMI) greater than or equal to 28 kg/m^2
2.2. Waist circumference greater than or equal to 90 cm
2.3. Stable body weight during the past 6 months (change of BMI less than 0.5 kg/m^2)
3. Aged between 18 - 25 years, male only

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. Have history of liver, kidney, hypertension, genetic disease, diabetes and coronary heart disease
2. Smoker
3. Taking correlated medications which could potentially influence the purpose of this study
4. Not taking vitamin and mineral supplements in the past 6 months

Date of first enrolment
01/02/2010

Date of final enrolment
30/04/2010

Locations

Countries of recruitment
China

Study participating centre
157 Baojian Road
Harbin
China
150081

Sponsor information

Organisation
Health College - Harbin Medical University (China)

ROR
https://ror.org/05jscf583

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China (China)

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration