

Glycometabolism and lipid metabolism in obese people by metabolomics technique

Submission date 24/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/05/2010	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

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 measure

Metabolic fingerprints

Secondary outcome measures

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

Overall study start date

01/02/2010

Completion date

30/04/2010

Eligibility

Key inclusion criteria

1. Normal weight group: body mass index between 18.5 kg/m² - 24 kg/m²
2. Obese group:
 - 2.1. Body mass index (BMI) greater than or equal to 28 kg/m²
 - 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/m²)
3. Aged between 18 - 25 years, male only

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

120

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)

Sponsor details

c/o Changhao Sun

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Sponsor type

University/education

Website

<http://yxzy.hrbmu.edu.cn/gongwei/home.asp.Public>

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 Wěiyuánhùi, NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

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