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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Contact details

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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/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

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 157 Baojian Road Nangang District Harbin China 150081 +86 0451 87502801 sun2002changhao@yahoo.com

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 Wěiyuánhuì, 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