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Effect of vitamin D treatment on the improvement of metabolic syndrome

Submission date	Recruitment status
20/12/2011	No longer recruiting
Registration date	**Overall study status**
16/01/2012	Completed
Last Edited	**Condition category**
16/09/2016	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Altered vitamin D levels are associated with an increased risk of obesity, high blood pressure and diabetes (also known as metabolic syndrome). Low levels of vitamin D (hypovitaminosis D) are also a risk factor for heart disease and death. The northern Chinese population have an increased risk of hypovitaminosis D due to their darker skin pigmentation and living at a northern latitude. Few studies have focused on the effect of vitamin D supplements on obesity and related metabolic disorders in Chinese populations. The aims of this study are to examine the relationship between vitamin D levels and obesity and other metabolic risk factors, and to find out whether vitamin D supplements improve metabolic disorders in patients with metabolic syndrome and hypovitaminosis D.

Who can participate?
People aged 35-60 who visit the healthcare department of Jinan Central Hospital for their annual health examination

What does the study involve?
Participants' weight, height, waist circumference and blood pressure are measured. A blood sample is collected for measurement of vitamin D, glucose (sugar), insulin, fat and cholesterol levels. Participants with metabolic syndrome and hypovitaminosis D are randomly allocated to take either vitamin D and calcium supplements or a placebo (dummy drug) for 12 weeks. Both groups receive a lifestyle intervention provided by a dietitian. The dietitian meets the participants at 2-week intervals to assess their compliance with the lifestyle intervention program and provide additional study products (vitamin D, calcium or placebos). At the end of the 12 weeks, the two groups undergo the same tests as at the start of the study.

What are the possible benefits and risks of participating?
All participants receive a lifestyle intervention which may improve their health and physical function. The participants who receive vitamin D and calcium supplements may improve their vitamin D levels. There are no known risks to participants.

Where is the study run from?
Jinan Central Hospital (China)

When is the study starting and how long is it expected to run for?
January to April 2012

Who is funding the study?
1. Science and Technical Bureau of Jinan (China)
2. Health Department of Shandong (China)

Who is the main contact?
Dr Xiao Yin

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
NCT

Study information

Scientific Title
Effect of vitamin D treatment on the improvement of metabolic syndrome: a randomized single-blind trial

Study objectives
1. Are the vitamin D levels associated with indices of adiposity and metabolic risk factors in a representative sample of the urban young and middle-aged non-diabetic adults residing in northern China?
2. Evaluate the prevalence of subclinical vitamin D deficiency in this cohort
3. Does vitamin D supplementation, in a randomized double-blind intervention trial, improve metabolic disorders in metabolic syndrome individuals with hypovitaminosis D.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee of Shandong University Affiliated Jinan Central Hospital, China, 14/12/2011 ref: 2011026

Study design
Cross-sectional cohort single-center interventional randomised double blind placebo-controlled crossover study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
Anthropometric measures (weight, height, waist circumference) and blood pressure will be measured on all participants. A fasting blood sample will be collected for measurement of serum 25-hydroxy vitamin D, plasma glucose, insulin, triglyceride, low density lipoprotein (LDL) cholesterol and high density lipoprotein (HDL) cholesterol concentrations.

For the randomized treatment portion of the study, 40-50 metabolic syndrome patients with hypovitaminosis D will be assigned, in a random double-blind manner, to receive either vitamin D treatment (vitamin D treatment group) or placebo (control group). Those in the vitamin D treatment group receive an oral dose of 500 IU vitamin D3 (cholecalciferol) and 1200mg calcium daily for 12 weeks. Both groups will be provided lifestyle intervention by a dietitian, At the end of the 12 weeks, subjects in the two groups will be re-evaluated for the same parameters measured at baseline.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Weight, height, waist circumference and blood pressure
2. Body mass index (BMI)
3. Serum 25(OH)D and insulin, measured by double antibody radioimmunoassay
4. Plasma glucose, triglycerides, and HDL cholesterol, measured by enzymatic colorimetric assay

Key secondary outcome(s))
LDL cholesterol, calculated using the Friedwald equation

Completion date
01/04/2012

Eligibility

Key inclusion criteria
1. Male and female participants
2. Aged 35-60 years old
3. Living in Jinan, China for more than 5 years
4. Employed in an office setting
5. Has had more than 13 years of education

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Use of vitamin D and calcium supplementation within 60 days of screening
2. Current use of cigarettes (self-report)
3. Alcohol abuse (defined as >14 drinks/week for men, >7 drinks/week for women)
4. Diagnosis of overt diabetes, cardiovascular disease or other systematic disease
5. Use of medications that influence vitamin D, glucose, lipid profiles or blood pressure
6. Engaging in more than 20 minutes of strenuous physical activity or exercise that causes excessive breathing and sweating more than once per week

Date of first enrolment
01/01/2012

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
China

Study participating centre
Shandong University
Jinan
China
250100

Sponsor information

Organisation
Shandong University (China)

ROR
https://ror.org/0207yh398

Funder(s)

Funder type
Government

Funder Name
Jinan Technology Star Program, Science and Technical Bureau of Jinan (China)

Funder Name
Shandong Province Medical and Health Development Program (China)

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?
Results article	results	09/09/2012		Yes	No