

# The differential effects of visceral fat reduction compared with subcutaneous fat reduction on parameters of the metabolic indices and adipocytokines

<b>Submission date</b> 18/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/10/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/10/2007	<b>Condition category</b> 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

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

1

# Study information

## Scientific Title

### Study objectives

The weight reduction with the change of fat distribution influence on the adipokines and metabolic indices.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the Institutional Review Board of Yondong Severance Hospital, Yonsei University College of Medicine (South Korea) on the 6th September 2006 (ref: 3-2006-0044).

### Study design

A prospective intervention study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Quality of life

## Participant information sheet

### Health condition(s) or problem(s) studied

Obesity

### Interventions

All patients received all three interventions for 16 weeks:

1. The subjects visited an obesity clinic twice per month and restricted their caloric intake to less than their usual intake by 600 kcal/day
2. All patients were encouraged to achieve the goal of five hours of aerobic exercise (physical activity of moderate intensity, such as brisk walking, light jogging or stationary ergometer usage) per week
3. They were also administered 10 - 15 mg of sibutramine (in the morning)

### Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Sibutramine

**Primary outcome measure**

The changes of body fat distribution and adipocytokines, determined by computed tomography scan and measured both before and 16 weeks after the weight reduction program.

**Secondary outcome measures**

The relationship of body fat distribution and adipocytokines, determined by computed tomography scan and measured both before and 16 weeks after the weight reduction program.

**Overall study start date**

06/09/2006

**Completion date**

31/05/2007

## **Eligibility**

**Key inclusion criteria**

1. Apparently healthy, either sex, aged 18 - 60 years
2. Non-smokers
3. Low alcohol consumers
4. Overweight or obese with an average Body Mass Index (BMI) of 23 kg/m<sup>2</sup> or greater

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

60 Years

**Sex**

Both

**Target number of participants**

52

**Key exclusion criteria**

1. A past history of cardiovascular disease
2. Diabetes
3. Moderate to severe hypertension (resting blood pressure greater than 170/100 mmHg)
4. Renal impairment (serum creatinine greater than 120  $\mu\text{mol/L}$ ) or overt proteinuria
5. Obesity caused by an endocrine disorder
6. Psychiatric disorders
7. Current pregnancy or breast-feeding
8. A body weight fluctuation of more than 5 kg in the previous six months
9. Taking any kind of medication

**Date of first enrolment**

06/09/2006

**Date of final enrolment**

31/05/2007

## Locations

**Countries of recruitment**

Korea, South

**Study participating centre****Department of Family Medicine**

Seoul

Korea, South

135-270

## Sponsor information

**Organisation**

Yonsei University College of Medicine (South Korea)

**Sponsor details**

250 Sungsan-Ro

Seodaemun-gu

Seoul

Korea, South

120-752

**Sponsor type**

University/education

**Website**

<http://medicine.yonsei.ac.kr/en/index.asp>

**ROR**

<https://ror.org/01wjejq96>

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

Yonsei University College of Medicine (South Korea) - faculty research grant (2006)

## **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